European Commission

JRC SCIENCE FOR POLICY REPORT

Revision of the European Ecolabel Criteria for Lubricants

Final Technical Report: Criteria proposal for revision of EU Ecolabel criteria

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July 2018

Joint Research Centre

EUR 29491 EN

JRC Science Hub
https://ec.europa.eu/jrc

JRC114383

EUR 29491 EN

PDF ISBN 978-92-79-98176-0 ISSN 1831-9424 doi:10.2760/58736

Seville: European Union, 2018

How to cite this report: Author(s), *Title*, EUR 29491 EN, Publisher, Publisher City, Year of Publication, ISBN 978-92-79-98176-0, doi:10.2760/58736, JRC114383

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1 INTRODUCTION

The objective of this project is to revise the existing EU Ecolabel criteria (Commission Decision 2011/381/EU[1]) for lubricant product group. The criteria were for the first time established in 2001 and the Decision currently in force is valid until the end of December 2018.

This technical report is intended to provide background information for the revision of the existing EU Ecolabel criteria for lubricants. The study has been carried out by the Joint Research Centre (JRC) with the technical support of LEITAT. The work is being developed for the European Commission's Directorate General for the Environment.

The main purpose of the technical report is to summarise the results of the preliminary analysis of the current criteria and to discuss if the criteria are still appropriate and up-to-date or if they should be revised, amended or some of them removed; and finally, and if any new criteria should be added.

This technical report is supported and complemented by the preliminary report[2] published in December 2016. The preliminary report includes scope and definition, market analysis, and technical analysis. Moreover, a first draft revision of the technical report (TR1.0)[3] was published in December 2016 and has built the basis for the first Ad-hoc Working Group meeting (AHWG1) which took place in February 2017. The result of this meeting was a second draft of the technical report (TR2.0)[4], which included the second criteria proposal based on information collected during the first consultation (i.e. through stakeholders' discussion at the 1st AHWG meeting, further stakeholder inputs following the meetings) and additional desk research.

The revision process has continued with a second AHWG meeting, organized in October 2017. The aim of the 2nd AHWG meeting was to discuss and further complete the second criteria proposal. As a result of this process this 3rd draft of the technical report (TR3.0) was prepared, which includes the latest criteria proposal along with the comments received during the consultation process.

Final written consultation took place in February 2018. After the consultation a final version of the report and criteria proposal has been produced.

This final report consists of:

- **Introduction** (Chapter 1): this section describes the goal and content of the document, the sources of information and the next steps in the project. It also summarizes the main findings from the preliminary report and the conclusions obtained regarding the scope definition and the key environmental aspects related to the product group of lubricants. This chapter has been complemented considering the input received in the 2nd stakeholder consultation and additional research.

[1] Commission Decision No 2011/381/EU of the European Parliament and of the Council of 24 June 2011 establishing the ecological criteria for the award of the EU Ecolabel to lubricants, available online at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011D0381

[2] Preliminary Report. Revision of European Ecolabel Criteria for Lubricants. December 2016. See: http://susproc.jrc.ec.europa.eu/Lubricants/documents.html.

[3] Draft Technical report EU Ecolabel Lubricants. December 2016. See: http://susproc.jrc.ec.europa.eu/Lubricants/documents.html.

[4] 2nd Draft Technical report EU Ecolabel Lubricants. September 2017. See; http://susproc.jrc.ec.europa.eu/Lubricants/documents.html.

- **Assessment and verification** (Chapter 2)**:** this section includes information on the type of documentation required to show compliance with the criteria that shall be provided by applicants and recognised by Competent Bodies.
- **Criteria proposal** (Chapter 3)**:** this section presents the final revised EU Ecolabel criteria for the lubricants product group. The proposal is written in a blue box and subsequently a rationale is given. A rationale consisting on a summary of main discussion points, research conducted during the revision and conclusions is provided for each criterion.
- **Impact of changes to criteria** (Chapter 4): this section consists of a summary of the main changes proposed for the revised criteria and potential implications on current licence holders and applicants.
- **Appendix I** includes the existing EU Ecolabel criteria in order to allow the reader to consult the text in force.
- **Annex** I is a table including all of the comments received during the last written consultation, together with responses and explanations on how they have been addressed in this final report.

1.1 Methodology and source of information

The approach followed in the revision of the EU Ecolabel for lubricants consists of the following elements:

- analysis of the current scope and criteria and a review of any relevant legislation;
- analysis of the lubricant market from a global and European perspective;
- technical analysis, in which environmental and health impacts are studied.

A brief description of these above-mentioned elements is given below:

Revision of the scope and definition: an overview of existing technical categories, and relevant legislation and standards has been done in order to identify aspects of the current criteria, which may require revision. Moreover, stakeholder feedback was obtained through a questionnaire on the current scope and definition. Other labelling schemes and other initiatives related to lubricants have been analysed in order to identify potential areas for harmonization.

Market analysis: the trend of global and European lubricant market has been analysed. Key figures and data have been collected in order to properly understand the current market of lubricants and the potential intake of the EU Ecolabel. The main source used for this work has been *Lubricants Market Analysis and Segment Forecasts to 2022*[5].

Technical analysis: the aim of the technical analysis is to provide information about potential impact of lubricants on the environment and human health. The entire life cycle of a lubricant has been assessed in order to identify the life cycle stages with the highest environmental impacts and those with the highest improvement potential. In addition, analysis of the main hazardous substances used in the lubricant sector has been done, and an identification of their environment and human health impacts has been conducted.

For this task, a critical review of published LCA studies has been performed. 12 Life Cycle Assessment studies (LCAs) have been screened in order to evaluate the quality and their suitability for the current work and classify them depending on four parameters: the scope, data, impact categories evaluated and conclusions/findings. Supplementary information was sought

[5] Lubricants Market Analysis and Segmented Forecasts to 2022. Grand view Research, Inc. 2015

about the sustainability considerations in the different cycle stages in order to cover all key aspects of the life cycle of lubricants. Moreover, the software SimaPro 8.0 and database Ecoinvent 3 has been used for analysing some of the cycle stages of lubricants.

In addition, a prioritisation methodology has been designed in order to consider all the multidimensional (e.g. market, technical, environmental, health) aspects that influence this revision. The prioritisation methodology has served as a basis to prepare a proposal of the revised scope attending to aspects including market, technical and environmental aspects, as well as to help us to identify the environmental hotspots associated to the categories included in the scope in order to set the revised criteria that target the main relevant environmental hotspots associated to this product group.

Two questionnaires have been sent out to all registered stakeholders in the initial stage of the revision process. A first questionnaire has been done about the current scope and definition, including also questions about the current criteria. The answers of the stakeholders (44 in total) have been presented in the preliminary and technical reports. In addition, a survey on *data requirements for existing criteria 3, 4 and 5* has been sent to stakeholders with the aim to obtain information on the current values of aquatic toxicity, biodegradation and bioaccumulation, and content of renewable materials for current and potentially labelled products.

The information obtained during this preliminary phase of the revision process has been included in the Preliminary Report published along with the 1st technical report, and constituted the basis of the 1st revised criteria proposal.

Both documents (preliminary report and technical report) have served as a basis for discussions with stakeholders in the AHWG meetings. In addition, competent bodies (CB) have been contacted to obtain additional information on certified lubricant products; and a number of stakeholders (lubricants producers, ingredients suppliers, other experts) have been consulted to submit information on technical performance details, as well as product composition.

At this stage, two AHWG meetings have been done, where the proposed criteria text was presented and discussed with the stakeholders. The opinions provided during the second consultation have been considered and comments taken into account in drafting of this 3rd version of the technical report. All previous discussions and revisions have been included in the previous drafts of this technical report (TR1.0 and TR2.0). The third criteria proposal is presented in this report including additional information and evidence collected in response to the comments received during and after the 2nd AHWG meeting.

1.2 Summary of the preliminary report and link to the EU Ecolabel criteria

The preliminary report summarises the analysis conducted in the initial stage of the revision of the criteria for the lubricants product group. This includes updating and revising the scope and definitions, analysis of the lubricants market, and a review of the scientific evidence to identify the main environmental impacts of lubricants. The sections below provide a summary of the findings from the preliminary report with a focus on the scope and on the key environmental aspects. Further details can be found in the report which is available at the project website: http://susproc.jrc.ec.europa.eu/Lubricants/documents.html.

The section has been updated for the TR3.0 considering the input received in the 2nd stakeholder consultation and additional research.

1.2.1 Product group name, scope and definitions

Product group name:
Lubricants
Final product group definition proposal:
A lubricant means a product that is capable of reducing friction, adhesion, heat, wear or corrosion when applied to a surface or introduced between two surfaces in relative motion, or is capable of transmitting mechanical power. The most common ingredients are base fluids and additives.

Final scope proposal:
The product group 'lubricants' shall comprise any lubricant falling within one of the following sub-groups: (a)the Total Loss Lubricants (TLL) sub-group, which shall comprise chainsaw oils, wire rope lubricants, concrete release agents, total loss greases and other total loss lubricants; (b)the Partial Loss Lubricants (PLL) sub-group, which shall comprise gear oils intended to be used in open gears, stern tube oils, two-stroke oils, temporary protection against corrosion and partial loss greases*;* (c)the Accidental Loss Lubricants (ALL) sub-group, which shall comprise hydraulic systems, metalworking fluids, gear oils intended to be used in closed gears and accidental loss greases. Note (to be included in the general assessment and verification text): Where grease can be used in TLL and PLL applications, as in the case in a multifunctional grease, criteria for TLL sub-group shall apply. Where grease can be used in PLL and ALL applications, but not as TLL, then the criteria for ALL sub-group shall apply. For gear oils used in open gears criteria applicable to the PLL sub-group shall apply while for gear oils used in closed gears criteria applicable to the ALL sub-group shall apply. When a gear oils can be used in both type of gears criteria applicable to the PLL sub-group shall apply

Final complementary definitions proposal:
(1) 'lubricant' means a product that is capable of reducing friction, adhesion, heat, wear or corrosion when applied to a surface or introduced between two surfaces in relative motion, or is capable of transmitting mechanical power. The most common ingredients are base fluids and additives; (2) 'base fluid' means a lubricating fluid which flow, ageing, lubricity and anti-wear properties, as well as its properties regarding contaminant suspension, have not been improved by the inclusion of additive(s); (3) 'additive' means a substance or mixture which primary functions are the improvement of one or several of the following aspects: flow, ageing, lubricity, anti-wear properties and contaminant suspension; (4) 'substance' means a chemical element and its compounds in the natural state or obtained by any production process, including any additive necessary to preserve its

stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

(5) 'total loss' means that the lubricant is fully released to the environment during use;

(6) 'partial loss' means that the lubricant is partially released to the environment during use and the non-released part can be recovered for re-processing, recycling or disposal;

(7) 'accidental loss' means that the lubricant is used in a closed system and can be released to the environment only incidentally and, after use, can be recovered for re-processing, recycling or disposal;

(8) 'chainsaw oil' means a lubricant that is used to lubricate the bar and chain on one or more types of chainsaw;

(9) 'wire rope lubricant' means a lubricant that is used to lubricate wire ropes which consist of several strands of metal wire held together to form a rope;

(10) 'concrete release agent' means a lubricant that is used in the construction industry to prevent freshly placed concrete adhering to a surface, usually plywood, overlaid plywood, steel or aluminium;

(11) 'grease' means a solid or semi-solid lubricant which contains a thickener in order to thicken or modify the rheology of the base fluid;

(12) 'gear oil' means a lubricant made specifically for transmissions, transfer cases, and differentials in automobiles, trucks, and other machinery;

(13) 'stern tube oil' means a lubricant used in the stern tube of a ship;

(14) 'two-stroke oil' means a lubricant used in two-stroke engines;

(15) 'temporary protection against corrosion' means a lubricant that is applied to a metal surface as a thin film in order to prevent water and oxygen from coming into contact with the metal surface;

(16) 'hydraulic systems' means a lubricant by means of which power is transferred in hydraulic machinery;

(17) 'metalworking fluid' means a lubricant designed for metalworking processes, such as cutting and forming, and whose main functions are cooling, reducing friction, removing metal particles, and protecting the work pieces, the tool, and the machine tool from corrosion;

Complementary definitions (To be placed in the ANNEX or User Manual)

'**LuSC-list**' or Lubricant Substance Classification list is a list of substances and brands that have been assessed by a competent body with regard the relevant requirements included in this Decision. The list is published on the EU Ecolabel website and the data can be used directly in the application form.

"**LoC**" or Letter of Compliance means a letter issued by one of the EU Ecolabel competent body indicating the assessment of a substance or brand used in a lubricant. It contains the same information as listed on the LuSC-list.

'**Critical concentration for the aquatic toxicity**' means the concentration of a substance at and above which it will cause adverse effects (chronic aquatic toxicity) or injuries (acute aquatic toxicity) to an aquatic organism in an exposure to that substance.

'**Acute aquatic toxicity**' means the intrinsic property of a substance to be injurious to an

aquatic organism in a short-term aquatic exposure to that substance.

'**Chronic aquatic toxicity**' means the intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism.

'**M-factor**' means a multiplying factor. It is applied to the concentration of a substance classified as hazardous to the aquatic environment acute category 1 or chronic category 1, and is used to derive by the summation method the classification of a mixture in which the substance is present.

'**Degradation**' means the decomposition of organic molecules to smaller molecules and eventually to carbon dioxide, water and salts.

'**Readily biodegradable**' means an arbitrary classification of chemicals which have passed certain specified screening tests for ultimate biodegradability; these tests are so stringent that it is assumed that such compounds will rapidly and completely biodegrade in aquatic environments under aerobic conditions. Substances are considered rapidly degradable in the environment if one of the following criteria holds true:

1. if, in 28-day ready biodegradation studies, at least the following levels of degradation are achieved:
   - tests based on dissolved organic carbon: 70 %;
   - a.tests based on oxygen depletion or carbon dioxide generation: 60 % of theoretical maximum.

These levels of biodegradation must be achieved within 10 days of the start of degradation which point is taken as the time when 10 % of the substance has been degraded, unless the substance is identified as an UVCB or as a complex, multi-constituent substance with structurally similar components. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days; or

2. if, in those cases, where only BOD and COD data are available, when the ratio of BOD5/COD is $\geq 0{,}5$; or

3. if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period.

'**Inherently biodegradable**' means a substance, which achieves the following level of degradation:

> 70 % after 28 days for inherent biodegradation test, or

> 20 % but < 60 % after 28 days in tests based on oxygen depletion or carbon dioxide generation.

'**Non-biodegradable**' means a substance which fails the criteria for ultimate and inherent biodegradability.

'**Highly insoluble**' means a substance which has a water solubility < 10µg/l according to OECD 105.

'**Slightly soluble**" means a substance which has a water solubility < 10mg/l according to OECD 105.

'**Bioconcentration factor**' (BCF) means the ratio of chemical concentration in an organism to that in surrounding water.

'**EC50**' is median effective concentration. It is the concentration that is estimated to cause some defined toxic effect to 50% of the test organisms; (e.g., death, immobilization, or serious incapacitation).

'**LC50**' means median lethal concentration. It is the concentration of material that is estimated to be lethal to 50% of the test organisms.

'**Octanol/water partition coefficient**' (K_{ow}) means the ratio of a chemical's solubility in n-octanol and water at equilibrium.

'**NOEC**' means 'no observed effect concentration'. It is the highest concentration at which no effect on test organisms is observed over a relatively long period in a chronic aquatic toxicity test.

'**Biochemical Oxygen Demand**' (BOD) means the quantity of oxygen utilized by micro-organisms growing under aerobic (oxygenated) conditions for the biochemical oxidation of organic substances under standard laboratory procedures which is usually 5 days (hence BOD5) but can be longer for specific purposes. BOD is usually expressed as a concentration (e.g., mg/l).

'**Chemical Oxygen Demand**' (COD) means the quantity of oxygen utilized in the chemical oxidation of an organic substance in water, as determined using a strong oxidant, under standard laboratory procedure, usually expressed in milligrams per litre (e.g., mg/l).

'**Theoretical Oxygen Demand**' (ThOD) is the calculated amount of oxygen required to oxidise an organic substance to its final oxidation products. However, there are some differences between standard methods that can influence the results obtained: for example, some calculations assume that nitrogen released from organics is generated as ammonia, whereas others allow for ammonia oxidation to nitrate. Therefore, in expressing results, the calculation assumptions should always be stated.

Rationale of the proposed name, scope and definitions

The existing **definition** [i.e. 'lubricant' means a preparation consisting of base fluids and additives] is quite broad, nevertheless there exist more complex lubricant compositions, which do not consist of base fluids and additives only but can be emulsions (e.g. metalworking fluids, and demoulding agents) or solid state compounds (e.g. fine powders to reduce friction) and therefore are not covered by the existing EU Ecolabel definition based on composition. This definition was proposed to be amended for the first proposal to include a reference to the functionality of the product with the aim to better explain which products are meant.

In the first proposal, no changes were introduced with regard the complementary definitions, contained in the current criteria text, since they were considered to be still valid.

In addition, for the lubricant types to be covered under the scope during this revision it was suggested to use the nomenclature of the lubricant families contained in the ISO 6743 classification, with the aim to better indicate what are the types of lubricants considered under the scope and to set clearer minimum technical performance requirements (to define a standard test per family or sub-family).

With regard to the **scope**, in the first survey it was proposed to extend the scope to cover the categories of the ISO 6743 currently not covered by the existing criteria (to increase the market share of the potential EU Ecolabel products). The preliminary report revealed that the existing scope only represents 16% of the total lubricants market.

For this revision, it was suggested to keep a focus on the total loss (lubricants physically released to the surrounding, their entry into environment is unavoidable and they are irretrievable), and high risk (of accident) lubricants (lubricants used in confined systems which are susceptible to accidental losses) and to extend the scope in order to cover a higher market share. In addition, the preliminary report highlighted that the environmental impacts of a lubricant product can occur in any stage of its life cycle (e.g. during raw material extraction or at the end of life), and not only from its potential release to the environment.

For this reason, it was considered reasonable to extend the scope to other lubricants not currently covered and that presents risk of accidental losses (accidental loss lubricants), and to other risks lubricants which are associated with other environmental impacts than those related to its potential release.

The approach proposed for the first AHWG meeting was to maintain the current lubricants included in the EU Ecolabel, and to extend the scope by taking into account the potential impact on the environment and human health during use and end-of-life, and the market share of each ISO family. The inclusion of all lubricant families in the same revision was considered impracticable due to the unfeasibility of developing criteria for such a wide number of categories in one revision process. In the light of the technical analysis, to set scope proposal a prioritizing methodology was defined in order to select the lubricants to be included in the new scope. The relevant points of the prioritization methodology were the following:

- potential for release to the environment,
- concerns regarding other aspects, like human health, disposal, possibility of recovery and reuse,
- market share and target end-consumers,
- availability of other environmental labelling schemes.

Several lubricant families currently not covered under the EU Ecolabel but are included in other labelling schemes were found. For instance, temporary protection against corrosion lubricants, named as “anti-rust lubricating oil” and 4-stroke engine oils are addressed in the Korea Ecolabel.

Using the prioritization methodology, the initial proposal on widening the scope was defined for the first AHWG meeting. The following lubricant families that are currently excluded from the EU Ecolabel scope and that were identified as being susceptible to be included during the revision process were:

- *metalworking fluids (MWFs)*: the metalworking fluids could be important due to accidental losses and due to the impact on human health from the worker's exposure point of view. Also the impacts linked with waste could be relevant from an environmental point of view.
- *temporary protection against corrosion*: they are often used in open systems and in environmentally sensitive areas. Sometimes they are not recovered after use and waste lubricant can be lost into the environment.
- *4-stroke engine oils*: they represent a high market share. In addition, they normally target end consumers and they present the issue of collecting of waste oil (especially at particular level).

In the **second proposal**, the scope was further defined; it was suggested to modify the scoping method grouping the lubricants in three categories:

The existing 5 categories:

- *Category 1: Hydraulic fluids and tractor transmission oils*

- *Category 2: Greases and stern tube greases*
- *Category 3: Chainsaw oils, concrete release agents, wire rope lubricants, stern tube oils and other total loss lubricants*
- *Category 4: Two-stroke oils*
- *Category 5: Industrial and marine gear oils*

Are suggested to be re-categorised under Total loss, Partial loss, and Accidental loss groups **(ALL, PLL, and TLL). ALL and PLL products can be recovered totally or in part, after use, for a proper recycling, re-refining or proper disposal. TLL products cannot be recovered, as they are totally released in the environment.**

Table 1.1 includes the lubricants subcategories or applications proposed to be included in this revision and also other subcategories that could fit under the three main categories and that could be discussed for future revisions. For most of the subcategories mentioned in the table their specific ISO family to which they belong is specified.

Table 1.1:Listing of a number of specific lubricant applications

	Accidental Loss Lubricants	Partial Loss Lubricants	Total Loss Lubricants
Proposed EU Ecolabel scope	- Enclosed gears oils (ISO C) - Hydraulic systems (ISO H) - **Metalworking fluids (ISO M) (new under this revision)** - ALL lubricating greases (e.g. overhead lines wire lubricating greases, enclosed gear lubricating greases) (ISO X)	- Two stroke oils (ISO E) - **Temporary protection against corrosion (ISO R) (new under this revision)** - PLL lubricating greases (e.g. railway pantographs lubricating greases, harbour slideway lubricating greases, some of open gear-bearing lubricating greases) (ISO X)	- Chainsaw oils, wire rope lubricants, (ISO A) - Concrete release agents - Open gear oils (ISO C) - TLL lubricating greases (e.g.drilling equipment lubricating greases, wheel flange railway lubricating greases, cotton picker spindle machinery lubricating greases, some open gear lubricating greases, stern tube lubricating greases) (ISO X) - Stern tube oils - Other total loss lubricants not specified within the scope (e.g. pneumatic tools (ISO P), rough applications, axles, railway points (ISO A))
Out of the scope	- Mould release (except concrete release) - Compressor oils (vacuum oils, screw, gas, rotary, piston, etc.) (ISO D) - Four stroke oils (ISO E) - Spindle bearings, bearings and associated clutches (ISO F) - Slideway oils (ISO G) - Heat transfer fluids, insulating oils (ISO Q) - Turbines (ISO T) - Heat treatment oils, quenching oils (ISO U)		

Table 1.2 shows the correspondence for each lubricant group in the existing scope in force to the proposed scope in the second revision:

Table 1.2:Correspondence among lubricants in current scope and second revision scope

	Current scope	Proposed scope
Cat 1	Hydraulic fluids	ALL, Hydraulic systems
Cat 1	Tractor transmission oils	ALL, Hydraulic systems
Cat 2	Lubricating greases	PLL, ALL, or TLL lubricating greases depending on application
Cat 2	Stern tube lubricating greases	TLL, lubricating greases
Cat 3	Chainsaw oils	TLL, Chainsaw oils
Cat 3	Concrete release agents	TLL, Concrete release agents
Cat 3	Wire rope lubricants	TLL, Wire rope lubricants
Cat 3	Stern tube oils	TLL, Stern tube oils
Cat 3	Other total loss	TLL, Other total loss lubricants
Cat 4	Two-stroke oils	PLL, Two-stroke oils
Cat 5	Industrial gear oils	TLL, Open gear oils (open applications) and ALL, Closed gear oils (closed applications)
Cat 5	Marine gear oils	ALL, Closed gear oils

Summarising, in the second proposal:

- Minor changes have been introduced in the definition in order to align to other EU Ecolabel product groups wording (i.e. products and ingredients). In addition, the lubricants included in the scope have been further defined in order to better indicate what the types of lubricants considered under the scope are.
- The existing five categories have been restructured in 3 main categories (TLL, PLL, and ALL) according to the potential of the lubricant to be released during use.
- The revised structure is simpler, as it allows the requirements to be set according to the impact associated to each main category and is comprehensive enough to allow the incorporation of new lubricant products in future revisions, avoiding the need for adding a new category for a new lubricant group.
- Definitions of the lubricants covered have been included. The ISO 6743 families have been used in order to better define the families included in each main category, however the limitations associated to these ISO standards (i.e some families are not fully developed and are not comprehensive enough to cover all products in the market, other families cover lubricants presenting applications that could be classified in several of the three suggested main groups…) have been considered and how to address these situations have been further explained in the scope text.
- Clarification on how to address other total loss lubricant category is proposed to be included in the User Manual.
- **Metalworking fluids** continue to be proposed for this second criteria version and have been included in the as ALL category.
- **Temporary protection against corrosion** also continues to be proposed and have been included as PLL
- **4T engine oils** proposed in first proposal have been finally withdrawn. Focus is placed on the existing scope and potential inclusion of less controversial lubricants (e.g. metalworking fluids and/or temporary protection against corrosion) in order to keep the current identity of the existing label and the current revision timeline. It is proposed that a label specifically for automotive oils could be considered in the future, if there is interest from the industry stakeholders.
- Complementary definitions section has been further completed with other relevant terms (most of them included in the existing User Manual).

In addition, the category 'other total loss lubricants' remains open as in current text in force. With this regard, it is suggested that the User Manual could include a quick Question / Answer information to be used in case of doubt. If an applicant comes to a Competent Body with a specific application of a lubricant that has not been specified in the scope and the CB is unsure if it could fit under 'other total loss lubricant' or is out of the scope, the 'recyclability question' can help. To the question: *can the product be recycled?* If the answer is no, then it is very likely a TLL and therefore could fits under 'other total loss lubricant' category.

- **Outcomes from and after the 2nd AHWG meeting**

At the second consultation, a number of stakeholders provided general feedback on the proposed scope. Several comments were received about the scope and the new categorisation of lubricants. Stakeholders commented that some of the lubricant categories included are not able to comply with new thresholds values proposed, or that they are not in a suitable category (sub-group).

Other comments point to stern tube lubricants and thrusters, which are the most conflictive families: *they should be PLL or ALL instead of TLL*. Stakeholders were asked about justification

for re-categorization of this family. In the second proposal, they are located in TLL since they are spilled out to the oceans.
One stakeholder said that MWF are used also in open systems. Moreover, stakeholders asked about the accomplishment of the revised threshold values for MWF and 2-stroke oils (which are linked to a high level of pollutant emissions and negative impacts). One stakeholder asked about the need to maintain the 2-stroke oils, due to the low number of products registered. One stakeholder suggested to move 2-stroke oils to the TLL. Given that there are registered products as 2-stroke oils and these products are partly and directly released to the environment, they are suggested to be kept in the PLL (the rest of the lubricant oil is burnt to CO_2 and H_2O, then released to the atmosphere, so the impact is different for the burnt portion.

One stakeholder suggested to completely eliminate greases from the PLL category, arguing that a lubricating grease is either formulated for external application (then being categorized as TLL), or formulated for a closed system (then categorized as ALL).

Finally, one stakeholder strongly approved the exclusion of re-refined oils from the scope, since they have a bad environmental performance concerning biodegradability and aquatic toxicity. Moreover, no comments asking for the inclusion of these lubricants (re-refined oils) have been received during the second consultation.

Several stakeholders questioned the classification of stern tube lubricants, either pointing to the similar characteristic of these lubricants with the hydraulic oils, or questioning directly its inclusion as total loss lubricants.

Other comments tackled very specific topics, as the name to be given to 'greases', as 'lubricating greases', so that they are not mixed up with 'kitchen' greases or fats.

Several stakeholders addressed the new classification approach ALL/PLL/TLL. There is general agreement that it is an easy to understand, open system. One stakeholder had trouble in having a precise understanding of Partial Loss Lubricants PLL, as the limit between ALL or TLL seemed to be fuzzy. The way to make it clear for the CB in order to have a proper criterion is to check whether the product can or can't be recovered for recycling. As example, the same stakeholder brings the Temporary Corrosion Protection, which can be properly disposed during the cleaning operation in the manufacturing plant, therefore they are considered PLL.

Full received comments and the respective answers can be consulted in the separated annex of comments published along with TR3.0.

- **Further research and main changes in the third proposal**

For the third proposal, a change has been suggested and accepted regarding a more precise name for greases, in the sense of always referring to these products as 'lubricating grease', so that there could not be any confusion with kitchen grease and/or fats.

One stakeholder proposed changing the hydraulic fluids from ALL to PLL. It is rejected as, in general, hydraulic fluids are used and recovered.

Another suggested treating the stern tube lubricants the same way hydraulic fluids are treated; the given argument is that both products are formulated in a similar way. The suggestion has been rejected because it is not the formulation of the product that gives the classification, but the point of application. The stern tube lubricant is slowly released into the ocean, that is the reason why ships do have large storage tanks for stern tube lubricant, so that the lost lubricant can be continuously refilled. There is no ship with 'recovered' stern tube lubricant; therefore, the suggestions to switch these lubricants from TLL to PLL have been rejected.

One stakeholder suggests including the 2-stroke oils as ALL, arguing that they are unintentionally burnt then released into the environment. This is only partly true, as the way a 2-stroke engine operates a small part of the mix (gasoline + oil) is released in the environment at every stroke of the engine.

In summary, **minor changes have been introduced within the scope and definitions** section for the third proposal mainly to clarify the text.

It is suggested that User Manual includes additional guidance on how to handle the categorisation of lubricants at application stage, especially for the situation of multifunctional greases and also for the lubricants that have not been explicitly specified in the scope but that could be categorised under Other total loss category.

- **Outcomes from last written consultation, Inter Service Consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within the scope and definitions section as a result of the final consultation:

- The term 'Critical concentration for the aquatic toxicity' which is relevant for criterion 2.1 has been partially modified to reflect that this concentration could refer either to acute or to chronic toxicity.
- With regards readily biodegradable definition, minor change in the definition has been introduced taking into consideration OECD definitions and CLP (chapter 4.1.2.9. Rapid degradability of organic substances). Any additional, more specific information regarding testing can be included in the User Manual.
- It is suggested to place stern tube oils and open gear oils under PLL sub –group as requested by several stakeholder and according to the evidence provided. They claimed that losses are very small in comparison to the entire oil volume and that collection and disposal on regular maintenance of the stern tube oils and open gear oils is normally carried out.
- Only minor wording format changes have been introduced**.**

1.2.2 Key environmental aspects and relation with the criteria proposal

A robust quantification of the overall environmental impact of lubricants would entail a detailed Life Cycle Assessment (LCA), with a scope covering manufacturing, use and fate at end of life, and with system boundaries encompassing petroleum, petrochemical, oleochemical and engineering industry activities. This would be a complex process, due to the very broad scope required, and also to some particular issues which are characteristic for the industry and the applications. One complication is that lubricants are typically manufactured as co-products in integrated product networks, based on petroleum refining, oleochemical refining or chemical processing.

In spite of the above-mentioned limitations the environmental assessment described in the chapter 3 of the Preliminary Report helped to identify the main areas of environmental concern from a life cycle perspective. This section summarises the main conclusions that can be extracted from the results revealed by LCA literature review and the supplementary environmental evidence.

In general, considering a cradle-to-grave approach, studies indicate that the release to the environment during use and disposal stages can be critical from an environmental point of view.

Nevertheless, most LCAs studies only cover cradle-to-gate scope and for this reason a quantification of the relevance of these stages is not feasible.

A summary of the main impact(s) according the life cycle stages is provided below:

Raw material extraction, transport and processing

Raw materials can be of high importance, since the extraction and processing (especially due to energy consumption) of these materials can have relevant impacts. Moreover, the composition of lubricants will condition the potential impact to the environment during and after their use, since formulation is related to inherent biodegradability and toxicity of the product.

Comparing **different base fluids:**

- In general **vegetable oil** (studies focus mainly in rapeseed and soybean base oils) brings advantages due its renewable origin and higher biodegradability. The highest impacts for vegetable oils are due to agriculture stage, so impacts highly depend on the various factors related to the cultivation of the crop. LCA comparative studies indicate lower energy consumption during processing and lower impacts for the global warming potential than mineral and synthetic oils.
- Regarding **synthetic oils (**studies focus mainly in PAOs lubricants), the refining/synthesis phase is the main contributor of impacts. The environmental impact of synthetic oils can be higher in the production phase, since greenhouse emissions of PAO are almost twice higher than those of mineral base oil, due to higher quantities of refinery gas burned for heat consumption and, in general, to a more energy consuming production process. However the characteristics of these lubricants allow a longer life of the lubricant and require less oil changes, leading to a decrease of environmental impacts per distance covered. Moreover, while they appear chemically similar to mineral oils refined from crude oil, PAOs do not contain the impurities or waxes inherent in conventional mineral oils.
- For **mineral base oil**, the highest contribution is due to the extraction phase.
- **Re-refined oils** bring environmental advantages. With modern re-refining technologies, CO_2 emissions can be reduced by more than 50% as compared to the conventional production of base oil.
- The environmental impact of **water base fluid** could occur mainly during the disposal of waste fluids.

In relation to **additives** (being between 0,1- 20% of formulation by weight), despite not being covered in most of LCA studies, they can have relevant contribution to life cycle impact of lubricants for some impact categories where impact from additives can be up to 50% of the total impact (in particular for carcinogens and mineral extraction).

With regard to **transport,** the relative impact seems to be of low relevance.

Manufacturing of lubricant, packaging and distribution

Manufacturing comprises blending of substances and it is a less complex process and with lower environmental impact than the processing of raw materials (where energy consumption is more relevant), although it can have significant contribution to some impact categories.

There is a broad range of types of **packaging** used, depending on the different applications and typologies of lubricants. Certain measures such as using recycled and recyclable, environmentally friendly materials, design for a correct use/application/resistance to spillage

and correct disposal might be easy to implement while bringing environmental benefits and circular economy principles to this product.

Use phase

The **use** stage of a lubricant product will highly determine its potential environmental impact, considering the probability of release to the environment and the consequences in terms of toxicity and impact on human health and the different environmental systems (especially for losses in sensitive areas). This impact is highly important since approximately 50% of all traditional lubricants are released into the environment during use, spills, or disposal. Any release of used oil to the environment, by accident or otherwise, threatens ground soil and surface waters with oil contamination endangering drinking water supply and aquatic organisms.

End-of-life

LCA studies indicate the disposal of used oil as the critical phase of the lubricant life cycle, which should be paid greater attention to in order to reduce potential environmental impact. Uncontrolled disposal of lubricant has adverse effect on the soils, aquatic life and drinking water. 50% of used oils will become waste oils potentially recoverable (the rest is lost during use; through leakages, exhaust emissions, etc.). Waste oils (WO) are hazardous waste as they contain additives, metals from engine wear, unburned fuel, polyaromatic hydrocarbons (PAH), particulates and water. Proper collection and subsequent re-refining is the best option from an environmental point of view; it has lower impacts than disposal (burning) and also it has associated environmental savings with respect to using new raw material for a lubricant.

After the 1st AHWG meeting stakeholders asked for more evidence and information about the impacts of different lubricants base fluids.

A further research was done in order to analyse more in depth base fluid alternatives.

Unfortunately, due to the varying scope and system boundaries of the available LCA studies and the particular issues which are characteristic of this industry, it has not been possible to perform a robust comparison between different base oils in the market. Moreover, current life cycle impact method does not cover properly toxicity and biodegradability, important issues to consider in case of spillage of the lubricant in the environment. For this reason, other environmental sources of information have been further investigated.

Nearly 50% of all lubricants sold worldwide pollute the environment, through spillage, evaporation, and total loss applications. Therefore it is proposed to focus on lubricants that are released to the environment during use. Against this, sources of information assessing biodegradability and toxicity which are environmental aspects of high relevance for lubricates which are lost into the environment were analysed. Following conclusions are drawn from this further assessment:

The biodegradability is mainly related with the **base fluid**, and not with the additives included in the formulation.[6]

- Vegetable oils are used in environmentally sensitive areas because they are biodegradable and have low toxicity. Moreover, due to their characteristics, they are perfect for total loss applications since the damage to the environment is low.[7]

[6] Eisentraeger, A., Schmidt, M., Murrenhoff, H., Dott, W., & Hahn, S. (2002). Biodegradability testing of synthetic ester lubricants—effects of additives and usage. Chemosphere, 48(1), 89-96.

- Synthetic oils have advantages over mineral oils, because the composition of the synthetic oils can be controlled, avoiding the use of harmful substances. Some of the newest synthetic lubricants from a mineral base oils have shown higher biodegradability than mineral lubricants: esters, PAO and PAG.[8]
- Re-refining of base oils causes less environmental impact than processing of base oil from crude oil. Comparison of the re-refined oils use with the synthetic oils use in lubricants shows that re-refined oils are a better environmental option (at least compared with the 30% of lubricant replaced used in the study).[9] However re-refined oils present high toxicity and low biodegradability, for this reason they are environmentally suitable only for non-total loss applications.

As a conclusion, mineral oils are not the best performing option for lubricants released to the environment during use due to their inability to biodegrade, and to the fact they remain in the ecosystem for a long time. This is very important, as release to the environment during use and disposal stages is critical from a lifecycle point of view. The use of non-biodegradable oils is especially problematic for lubricants used for total loss applications. Renewable oils, due to their natural origin and synthetic oils that can be fine-tuned during its synthesis to have a proper biodegradability and toxicity level seems to be best options for loss lubricants.

It is important to note that not all renewable raw materials are sustainable, there are different issues influencing the sustainability of the bio-based products. In particular, vegetable oils large impacts are produced during the agricultural stage, acting in the production method the environmental performance of vegetable lubricants could improve: cultivation practices, energy used in the production process, use of significant amounts of water, fertilizers and pesticides, etc. In this case, the most effective way of improving environmental performance is to encourage farmers to use good, sustainable agricultural practices. Therefore, some of the disadvantages associated to bio-based could be overcome by introducing criteria addressing aspects related to the sourcing. The impact of raw materials used could be reduced ensuring that vegetable oils comes from a sustainably management plantation, avoiding the impact of using pesticides or the unsustainable crop overexploitation.

In the light of the information contained in the preliminary report, the feedback received and further evidence collected, the main environmental areas of relevance and the areas of improvement of the existing criteria that have been addressed in more detail in this technical report and previous versions (TR1.0 and TR2.0) are summarised in the following table:

[7] OECD series on emission scenario documents Number 10: Emission scenario document on lubricants and lubricant additives. Environment directorate joint meeting of the chemicals committee and the working party on chemicals, pesticides and biotechnology, ENV/JM/MONO(2015)4, available online: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2015)4&doclanguage=en

[8] Mitigating Environmental Impact of Petroleum Lubricants- Ignatio Madanhire · Charles Mbohwa

[9] Ecological and energetic assessment of re-refining used oils to base oils: Substitution of primarily produced base oils including semi-synthetic and synthetic compounds. GEIR - Groupement Européen de l'Industrie de la Régénération, 2005, available online: http://www.geir-rerefining.org/documents/LCA_en_short_version.pdf.

Table 1.3:Link between the environmental aspects identified (LCA and non-LCA impacts) and the EU Ecolabel criteria

Existing EU Ecolabel criteria	Criteria second revised proposal	Environmental aspects	
Criterion 1. Excluded or limited substances and mixtures	Criterion 1. Excluded or limited substances	Hazardous substances Emission to soil/ water	It limits the hazardous substances that can be included in the product, limiting environmental and health risks for users.
Criterion 2. Restricted substances			
Criterion 3. Additional aquatic toxicity requirements	Criterion 2. Aquatic toxicity		It ensures that the overall aquatic toxicity is limited.
Criterion 4. Biodegradability and bioaccumulative potential	Criterion 3. Biodegradability and bioaccumulative potential		It ensures that the ingredients are biodegradable and will not persist in water.
Criterion 5. Renewable raw material	---------		
	Criterion 4. Origin, traceability and advertising of renewable ingredients	Raw materials extraction and processing	It promotes that renewable ingredients used for the lubricant manufacturing comes from sustainable origin.
	Criterion 5. Packaging	Raw materials extraction and processing Spillage during use phase	It ensures prevention of spillage during use and promotes the use of recycled plastics.
Criterion 6. Minimum technical performance	Criterion 6. Minimum technical performance	Efficiency during use	It guarantees that the product meets certain quality (technical performance) requirements foreseen for the different applications.
	Criterion 7. Consumer information	Waste generation and disposal	It reminds consumers to dispose of the packaging in a responsible manner.
Criterion 7. Information on EU Ecolabel	Criterion 8. Information on EU Ecolabel		It informs consumers on the environmental benefits associated with the product, in order to encourage the purchase of the product.

1.3 Proposed framework for the revision of the EU Ecolabel criteria and main changes

The proposed criteria are aimed to cover the different life stages and assessing the hot spots and key parameters identified in the preliminary report.

For the first AHWG meeting some criteria were suggested to be merged due to technical reasons, whereas other criteria have been modified in content but maintaining the structure. Moreover, some additional criteria were proposed in order to cover certain aspects not addressed through the current criteria and to be consistent with the revised scope. After the first AHWG consultation the criteria proposal was modified according the stakeholder comments and further research. The following table shows the changes in the criteria structure proposed along the revision:

Table 1.4:Comparison of the criteria structure

Existing EU Ecolabel criteria	Revised criteria proposal
Criterion 1. Excluded or limited substances and mixtures	Criterion 1. Excluded or limited substances
Criterion 2. Restricted substances	
Criterion 3. Additional aquatic toxicity requirements	Criterion 2. Aquatic toxicity
Criterion 4. Biodegradability and bioaccumulative potential	Criterion 3. Biodegradability and bioaccumulative potential
Criterion 5. Renewable raw material	-----
	Criterion 4. Origin, traceability and advertising of renewable ingredients
	Criterion 5. Packaging
Criterion 6. Minimum technical performance	Criterion 6. Minimum technical performance
	Criterion 7. Consumer information regarding use and disposal
Criterion 7. Information on EU Ecolabel	Criterion 8. Information on EU Ecolabel

2 ASSESSMENT AND VERIFICATION

Assessment and verification

(a) Requirements

The specific assessment and verification requirements are indicated within each criterion.

Where the applicant is required to provide the competent bodies with declarations, documentation, analyses, test reports, or other evidence to show compliance with the criteria, these may originate from the applicant and/or their supplier(s), as appropriate.

Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories (General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)) or with the principles of Good Laboratory Practice (GLP); and verifications by bodies that are accredited in accordance with the relevant harmonised standard for bodies certifying products, processes and services. Accreditation shall be carried out in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council([10]).

Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.

Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications or site visits.

As a prerequisite, the product shall meet all applicable legal requirements of the country or countries in which the product is intended to be placed on the market. The applicant shall declare the product's compliance with this requirement.

The Lubricant Substance Classification list (LuSC list), available on the EU Ecolabel website[11], contains substances and brands that have been assessed by a competent body with regard to the relevant requirements included in this Decision and the data can be used directly in the application process.

A Letter of Compliance issued by one of the EU Ecolabel competent bodies can be used directly in the application process.

A list of all intentionally added substances and/or formed intentionally after any chemical reaction in the applied lubricant at or above the concentration of 0,010% weight by weight in the final product shall be provided to the competent body, indicating the trade name (if existing), the chemical name, the CAS no., the ingoing quantity, the function and the form present in the final product formulation. All listed substances present in the form of nanomaterials shall be clearly indicated on the list with the word ‘nano’ written in brackets.

For each substance listed, the Safety Data Sheets (SDS) in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council([12]) shall be provided. Where an SDS is not available for a single substance because it is part of a mixture, the applicant shall provide the SDS of the mixture.

(b) Measurement thresholds

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[10] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

[11] http://ec.europa.eu/environment/ecolabel/

12 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

Assessment and verification
Compliance with the ecological criteria is required for the final product and its constituent substances that are intentionally added and/or formed intentionally after any chemical reaction in the applied lubricant as indicated within each criterion. In addition, the total fraction of the listed substances where the formulated criteria 2 and 3 do not apply shall remain below 0,5 % (w/w). **Note:** Where grease can be used in both, TLL and PLL applications (as in the case of multifunctional grease), criteria applicable to the TLL sub-group shall apply. If grease can be used as PLL and ALL, but not as TLL, then the criteria applicable to the PLL sub-group shall apply. For gear oils used in open gears criteria applicable to the PLL sub-group shall apply while for gear oils used in closed gears criteria applicable to the ALL sub-group shall apply. When a gear oils can be used in both type of gears criteria applicable to the PLL sub-group shall apply.

Rationale of proposed General text on Assessment and Verification

The assessment and verification text refers to the different types of evidence that is considered relevant as a proof of compliance for each criterion. The text has been revised to harmonize it as far as appropriate, with the text which is included in the most recently adopted EU Ecolabel criteria.

The EU Ecolabel Regulation (EC) No 66/2010 indicates that competent bodies shall preferentially recognize verifications performed by bodies which are accredited under the EN 45011. However, this standard is nowadays phased-out since it has been substituted by ISO/IEC 17065:2012: Conformity assessment - Requirements for bodies certifying products, processes and services. For this reason, certification bodies are no longer accredited in accordance with these requirements. A new statement has been included in the text making reference to the Regulation (EC) 765/2008 of the European Parliament and of the Council.

Where appropriate, test methods other than those indicated for each criterion may be used if the Competent body assessing the application accepts their equivalence. Furthermore, a note has been included clarifying that in the special cases when grease products have different applications, the precautionary principle applies and it shall be treated as TLL for EU Ecolabel purposes as the 'more restrictive' category.

Main comments received from stakeholders during the revision with regard the assessment and verification section are summarized below:

- Proposal to delete the reference to the function and form present in the final product. However, the reference to the function and form present in the final product has been maintained in order to enable traceability of nanomaterials present in products based on a precautionary principle. The same horizontal approach has been followed in other product categories.
- Proposal to delete the prerequisite that the applicant shall meet all applicable legal requirements of the country/ies in which the product is placed on the market. This comment has been rejected as the legal pre-requisite is horizontal for EU Ecolabel products.
- Proposal to modify the text in order to include that laboratories that can demonstrate compliance with ISO 17025 are technically competent to perform specific tests for

which they hold accreditation. The text has been modified according to the comment and to the preferred options for laboratory choice included in the existing User Manual.

- In addition, it has been specified, as mentioned in current User Manual that impurities stated in the SDS should be treated as intentionally added substances.

No relevant changes have been introduced in the general assessment and verification since first proposal. Section *(b) Measurement thresholds* has been simplified considering that the specific measuring thresholds are indicated within each requirement.

- **Outcomes from last written consultation, Inter Service Consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in the general assessment and verification section as a result of the final consultation:

- first of all, for clarity it was added that Letter of Compliance issued by one of the EU Ecolabel competent body can be used directly in the application process,
- In addition, text related to the impurities has been transferred to criterion 1 as it only applies to this criterion.
- A note has been introduced to clarify how to handle the gear oils depending on the declared use.

3 CRITERIA PROPOSAL

3.1 CRITERION 1: Excluded or limited substances

Final proposal for criterion 1: Excluded or limited substances

For the purpose of criterion 1 impurities stated in the SDS, whose presence in the final product equals or exceeds 0.010%, shall comply with the same requirements as the intentionally added substances.

1 (a) Hazardous substances

(i) Final product

The final product shall not be classified in accordance with any of the hazard statements included in Table 1.

(ii) Substances

Substances that meet the criteria for classification with the hazard statements listed in Table 1 shall not be intentionally added or formed in the final product as specified by the respective limit values.

Where stricter, the generic or specific concentration limits determined in accordance with Article 10 of Regulation (EC) No 1272/2008([13]) shall take precedence.

Table 1. Restricted hazard statements

Hazard statement([13])	**Limit value**
H340 May cause genetic defects	≤ 0.010 % weight by weight per substance in the final product
H350 May cause cancer	
H350i May cause cancer by inhalation	
H360F May damage fertility	
H360D May damage the unborn child	
H360FD May damage fertility. May damage the unborn child	
H360Fd May damage fertility. Suspected of damaging the unborn child	
H360Df May damage the unborn child. Suspected of damaging fertility	
H341 Suspected of causing genetic defects	
H351 Suspected of causing cancer	
H361f Suspected of damaging fertility	
H361d Suspected of damaging the unborn child	
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child	
H362 May cause harm to breast fed children	
H300 Fatal if swallowed (oral)	
H310 Fatal in contact with skin (dermal)	
H330 Fatal if inhaled (inhal.)	
H304 May be fatal if swallowed and enters airways	≤ 0.5 x Final product classification limit for H304([13])
H301 Toxic if swallowed	< Final product classification limit for H301([13])
H311 Toxic in contact with skin	< Final product classification limit for H311([13])

[13] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

H331 Toxic if inhaled	< Final product classification limit for H331([13])
EUH070 Toxic by eye contact	≤ 0.010 % weight by weight per substance in the final product
H370 Causes damage to organs	
H372 Causes damage to organs through prolonged or repeated exposure	
H371 May cause damage to organs	
H373 May cause damage to organs through prolonged or repeated exposure	< Final product classification limit for H373([13])
H335 May cause respiratory irritation	≤ 0.010 % weight by weight per substance in the final product
H336 May cause drowsiness or dizziness	< Final product classification limit for H336([13])
H317: May cause allergic skin reaction	< Final product classification limit for H317([13])
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	≤ 0.010 % weight by weight per substance in the final product
H314 Causes severe skin burns and eye damage	< Final product classification limit for H314([13])
H315 Causes skin irritation	< Final product classification limit for H315([13])
H318: Causes serious eye damage	< Final product classification limit for H318([13])
H319 Causes serious eye irritation	< Final product classification limit for H319([13])
H400 Very toxic to aquatic life	≤ 0.5 x Final product classification limit for H400([13])
H410 Very toxic to aquatic life with long-lasting effects	≤ 0.5 x Final product classification limit for H410([13])
H411 Toxic to aquatic life with long-lasting effects	< Final product classification limit for H412([13]) and H413([13])
H412 Harmful to aquatic life with long-lasting effects	
H413 May cause long-lasting effects to aquatic life	
H420 Harms public health and the environment by destroying ozone in the upper atmosphere	≤ 0.010 % weight by weight per substance in the final product
EUH029 Contact with water liberates toxic gas	
EUH031 Contact with acids liberates toxic gas	
EUH032 Contact with acids liberates very toxic gas	
EUH066 Repeated exposure may cause skin dryness or cracking	< Final product classification limit for EUH066([13])

Note: where final product classification limit (or 0.5 x Final product classification limit) is mentioned, the maximum total concentration of all classified substances with the specific hazard statement(s) shall be considered.

This criterion does not apply to substances covered by Article 2(7)(a) and (b) of Regulation (EC) No 1907/2006([12]) which sets out criteria for exempting substances within Annexes IV and V to that Regulation from the registration, downstream user and evaluation requirements. In order to determine whether that exclusion applies, the applicant shall screen any intentionally added/formed substance at or above the concentration of 0.010% weight by weight in the final product.

1 (b) Specified restricted substances

The substances listed below shall not be intentionally added or formed at or above the concentration of 0.010% weight by weight in the final product:

- Substances appearing in the Union List of priority substances in the field of water policy in Annex X to Directive 2000/60/EC of the European Parliament and of the Council([14]) as amended by Decision No 2455/2001/EC of the European Parliament and of the Council([15]) and the OSPAR List of Chemicals for Priority Action (http://www.ospar.org/work-areas/hasec/chemicals/priority-action);
- Organic halogen compounds and nitrite compounds;
- Metals or metallic compounds with the exception of sodium, potassium, magnesium and calcium. In the case of thickeners, also lithium and/or aluminium compounds may be used up to concentrations limited by the other criteria included in the Annex to this Decision.

1 (c) Substances of very high concern (SVHCs)

The final product shall not contain any intentionally added/formed substances that have been identified in accordance with the procedure described in Article 59(1) of Regulation (EU) No 1907/2006([12]), which establishes the candidate list for substances of very high concern at or above the concentration of 0.010% weight by weight in the final product.

Assessment and verification:

The applicant shall provide a signed declaration of compliance with above sub-requirements, supported by declarations from suppliers, if appropriate; and the following supporting evidence:
To demonstrate compliance with 1(a)(i) the applicant shall provide the SDS of the final product.
To demonstrate compliance with 1(a)(ii), 1(b) and 1(c) the applicant shall provide:

- SDS of intentionally added mixtures and their concentration in the final product.
- SDS of intentionally added substances and their concentration in the final product.

For substances exempted from requirement 1(a)(ii) (see Annexes IV and V to Regulation (EC) No 1907/2006), a declaration to this effect by the applicant shall suffice to comply.
For requirement 1(c) reference to the latest list of substances of very high concern shall be made on the date of application.

The above evidence can also be provided directly to Competent Bodies by any supplier in the applicant's supply chain.

Rationale of the proposed criterion text

Technical analysis showed that the chemicals used in the formulation of the product contribute significantly to the overall environmental impact of lubricants. The aim of the existing criteria in force (i.e. *1 Excluded or limited substances and mixtures* and *2 Exclusion of specific substances)* is to limit toxic or harmful substances, thus ensuring that the EU Ecolabel is only awarded to the least environmentally impacting products.

The **first proposal** consisted in the 3 sub-requirements summarized below:

- *Requirement 1 (a) Hazardous substances*, is directly linked to the requirements given in the EU Ecolabel Regulation (EC) No 66/2010 in Article 6(6) which states: "*the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction in accordance with Regulation (EC) No 1272/2008*".

[14] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).
[15] Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC (OJ L 331, 15.12.2001, p 1).

Following a strict interpretation of the Regulation text, it was suggested in the first proposal to restrict in the EU Ecolabel classified ingredients at substance level. Therefore the text was aligned to the recently voted criteria for the detergents product groups. It was proposed to eliminate the general derogation to the lowest classification limit that would trigger the classification of the final product (as it is in general done in the current criteria) and to grant derogations only to specific substances or group of substances following a thorough analysis.

- *Requirement 1 (b) Specified restricted substances*

This sub-requirement was based on the existing criterion *2 Exclusion of specific substances*, which asks that several groups of substances (OSPAR List, organic halogen compounds, nitrite compounds and metallic compounds) are restricted above specified concentrations in the final product. No changes were proposed compared to the current criteria in force for the first AHWG meeting.

- *Requirement 1 (c) Substances of very high concern (SVHCs)*

Sub-criterion (c) is also directly linked to the EU Ecolabel Regulation (EC) No 66/2010, which states that no substances of very high concern (SVHC) can be present in EU Ecolabel products. "*No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 (REACH) and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight)*".

In the first proposal, it was suggested to align the wording to detergents product group restricting totally the presence of SHVC in the final product. However, if derogation requests are received for SVHC presence in the final product below 0.010% w/w (which is existing limit in force for lubricants), reformulation of the requirement was suggested to be considered.

The updated list of SVHCs is available on the European Chemicals Agency website: http://echa.europa.eu/web/guest/candidate-list-table. The applicant is asked to refer to the latest version of this list at the date of application.

For the **second proposal,** developed following the 1st AHWG meeting, Table 1 in criterion 1 (a) was modified to include a column that reflects the Blue Angel approach and where certain hazards were derogated up to a maximum of half of the relevant concentration that would lead to classification of the final product.

No changes were introduced in criteria 1 (b) and 1 (c) compared to the first proposal.

- **Outcomes from and after the 2nd AHWG meeting**

Comments received from stakeholders during and after the 2nd AHWG meetings were mainly focused on the difficulty to apply the approach of restricting the EU Ecolabel hazards at substance level as already mentioned in the 1st AHWG meeting. Further, they referred to the impact of the revised requirement on the LuSC list[16] and the potential loss of current licenses if the proposed criterion is implemented.

[16] "LuSC-list" or Lubricant Substance Classification list is a list of substances and brands that have been assessed on its biodegradation/bioaccumulation, aquatic toxicity, renewability and exclusion lists of substances by a competent body. The assessment is only based on a maximum treat rate allowed in a lubricant. The list is published on the EU Ecolabel website and the data can be used directly in the application form. More information available on line at: http://ec.europa.eu/environment/ecolabel/documents/lusclist.pdf

With regard the Blue Angel approach, it was suggested to revise the alignment proposed in TR 2.0 and base the limitation of the hazardous substances following the same approach as defined in RAL-UZ 178[17], which seems to be a kind of compromise solution.

With regards to criterion 1 (c) some comments were received objecting the absence of any minimum limit for SVHCs due to the limit value of detection of the analytical techniques to determine their presence and due to the issue of presence of impurities.

- **Further research and main changes in third proposal:**

Against this background, the additional work after the second consultation has been focused on the controversial issues with regard the comments received.

Further research and main changes in the third proposal are described below according to each specific sub-requirement.

Requirement 1 (a) Hazardous substances

With regards to the requirement 1 (a) related to hazardous substances, the possibility to set a more harmonized approach with other product groups under the EU Ecolabel, while at the same time not being excessively strict for the current licenses, has been explored further. Moreover, the impact of the revised requirement on the LuSC list has also been assessed.

Since no derogation requests were received in the second call for derogations, stakeholders and CBs have been further consulted in order to evaluate the impact of the revised requirements on the number of the current EU Ecolabel products and on the LuSC list; and the possible derogations needs.

The consultation to stakeholders has been focused on:

1. Compilation of the Safety Data Sheets (SDS) of the commercial brands included in part 2 of the **LuSC list**.
2. Compilation of information about the hazard profile of all intentionally added substances above 0.010% present in the **current EU Ecolabel lubricants**.

1. LuSC List assessment

In the first case, the **assessment of potential compliance of the substances present in the LuSC list with regards to the requirement for limitation of hazardous substances present at the concentration at or above 0.01% in the final product** (Horizontal EU Ecolabel threshold) has been carried out. Companies included in the LuSC list have provided to JRC the SDS of substances and mixtures within the list in order to allow JRC to assess the potential implementation of the EU Ecolabel article 6(6) and 6(7). The summary of the hazard profile assessment of the products included in the **LuSC-list** considering compliance with the horizontal 0.01% threshold according to Article 6(6) and 6 (7) of EU Ecolabel Regulation (EC) No 66/2010 is detailed below:

- **Substances included in the part I of the LuSC list (74 substances):** All substances included have been assessed. **88%** of the substances included in part I of the LuSC list are not classified according to any of the EU Ecolabel Hazards defined for Lubricants. All the rest (**12%**) are classified according to following hazards: **H315, H318, H319, H400 and H413**.

[17] Basic criteria for award of the Blue Angel Eco-label for Biodegradable Lubricants and Hydraulic Fluids according to RAL-UZ 178. More information available online at: https://www.blauer-engel.de/en/products/business/schmierstoffe-hydraulikfluessigkeiten/hydraulikfluessigkeiten

If horizontal approach applies: 9 out of 74 substances included in part I of the LuSC list would be subject to 0.01% concentration limit in the final product.

- **Substances included in the part II - brands of the LuSC list [194 substances (additionally there are 21 brands where it is unclear if these are substances or mixtures)]: 38-42%** (considering the uncertainty due to unclear brands) of substances included in the part II - brands of the LuSC list. Out of those, **69%** are not classified according to any of the EU Ecolabel Hazards defined for lubricants. All the rest (**31%**) are classified according to following hazards: **H314, H315, H317, H318, H319, H361f, H361d, H400, H410, H411, H412 and H413**.
  If horizontal approach applies: 81 out of [194-215] substances were assessed. 25 out of 81 assessed substances included in part II of the LuSC list would be subject to 0.01% concentration limit in the final product.

- **Mixtures included in the part II- brands of the LuSC list (31 mixtures (+21 brands unclear if substances or mixtures)): 54-90%** (considering the uncertainty due to unclear brands) of the mixtures in the part II- brands of the LuSC list have been assessed. 28 SDSs have been received. When mixtures are considered, the SDSs are not a sufficient source of information to evaluate the presence of substances classified according to EU Ecolabel Hazards above 0.01% in the mixtures. In the SDSs for mixtures there is a gap of information related to hazardous substances at concentrations below the threshold that would lead to the classification of the mixture. An excel file was prepared in order to request the relevant information. However companies did not provided additional information, thus **the assessment of mixtures in the majority of cases has not been possible** since the SDSs are not sufficient source of information to evaluate the presence of substances classified according to EU Ecolabel Hazards above 0.01% in the mixtures.

  Nevertheless, we can conclude that:

  - As minimum, **50% of the mixtures assessed are classified** according to the EU Ecolabel hazards. The current "proposed maximum treat rate %" that indicates the maximum % allowed of this product in order to comply with existing EU Ecolabel criterion 1 would need to be significantly reduced.
  - In cases where a mixture is not classified as hazardous, it has not been possible to conclude the non-presence of substances with EU Ecolabel hazards above 0.01% since any additional information has not been provided by industry to certify it.
  - The **list of hazard statements** of substances present in the mixture that are not compliant with revised horizontal 0.01% threshold* are: **H373, H304, H314, H315, H317, H318, H319, H400, H410, H411, H412 and H413.**

  * Only taken into account the hazard statements that trigger the classification of the mixture. It is assumed that in the majority of cases the concentration limits according to Annex I to CLP regulation are above 0.01%.

In cases where no harmonized classification is available, the classification has been based on the major number of notifications provided to the ECHA C&L inventory.

2. Current licenses assessment

The **hazard profile assessment of all intentionally added substances above 0.01% present in the current EU Ecolabel lubricants** has been also analyzed. The compilation of information about the hazard profile of current EU Ecolabel lubricants has been mainly focused on competent bodies with major share of licenses. To date, six answers were received, which represents approximately 73% of all licenses. An overview of the hazard profile of all substances above 0.01% present in the lubricants assessed is shown in the table below based on the results of the "excel survey". It should be noted that a quantitative assessment based on the number of affected current EEL products has not been possible due to two main reasons:

- Confidentially agreements with the producers. Instead of sending the complete composition of each EEL product, CBs have filtered all the classified substances of all products together, listed them and stated the highest fraction present. Thus, only a general overview has been provided.
- In addition, it should be noted that different EU Ecolabelled products can be covered by the same application (license) but the applicant has to specify the product composition. Nevertheless, only ranges of concentration have been provided by CBs without any information about how many products are covered by the license.

In summary, a qualitative hazard profile assessment has been carried out. The hazard statements not compliant with the horizontal 0.01% threshold are listed below.

Table 3.1. EU Ecolabel hazard statements presented by substances above 0.01% on current assessed licenses

EU Ecolabel Hazards statements presented by substances above 0.01% on current assessed licences	
Health Hazard Statement	**Environmental Hazard Statement**
H319	H411
H311/H331/H301	H412
H315	H413
H317	H400
H373	H410
H304	
EUH066	
H372	
H314	
H318	
H336	

The following below shows the comparison between the list of the EU Ecolabel hazard statements present in currently assessed licenses and those included in the LuSC List (either directly as substances or within the mixtures).

Table 3.2. EU Ecolabel hazard statements present on current assessed licenses and in the LuSC-list

EU Ecolabel hazard statements present on current assessed licences and in the LuSC List		
Hazard statements	**Assessed lubricants**	**LuSClist**
H319	√	√
H311/H331/H301	√	
H315	√	√

H317	√	√
H373	√	√
H304	√	√
EUH066	√	
H372	√	
H314	√	√
H318	√	√
H336	√	
H361f		√
H361d		√
H411	√	√
H412	√	√
H413	√	√
H400	√	√
H410	√	√

Additionally, the **approach followed in Blue Angel** has also been further explored in order to propose the alignment mentioned in TR 2.0 and the possibility to base the limitation of the hazardous substances following the same approach as defined in RAL-UZ 178, which seems to be a kind of compromise solution and gained support from the stakeholders. Thus, the Blue Angel approach related to substances restrictions due to their intrinsic properties according to European chemical law (REACH, CLP) has been summarized in Table 3.3 below.

The main aim of the third proposal was to ensure more flexibility to certain substances classified with those hazard statements that currently would not comply with the horizontal 0.01% threshold based on the results of the hazard profile assessment of current assessed LuSC-list products and EU Ecolabelled lubricants (see Table 3.2 above).

Table 3.3. Blue Angel approach for lubricants related to substances restrictions due to their intrinsic properties according to European chemical law (REACH, CLP)

Hazard statement according to the CLP Regulation		Limit Value [%] for substances[18] in the final product[19] *	Limit Value [%] for impurities in the substance[20]
Muta. 1[A,B]	H340	0	≤ Classification limit
Muta. 2	H341	0	≤ Classification limit
Carc. 1[A,B]	H350	0	≤ Classification limit
Carc. 1[A,B]	H350i	0	≤ Classification limit
Carc. 2	H351	0	≤ Classification limit
Repr. 1[A,B]	H360F	0	≤ Classification limit
Repr. 1[A,B]	H360D	0	≤ Classification limit
Repr. 1[A,B]	H360FD	0	≤ Classification limit
Repr. 1[A,B]	H360Fd	0	≤ Classification limit
Repr. 1[A,B]	H360Df	0	≤ Classification limit
Repr. 2	H361f	0	≤ Classification limit
Repr. 2	H361d	0	≤ Classification limit
Repr. 2	H361fd	0	≤ Classification limit

[18] This also applies to possible degradation products where it must be assumed that they possess carcinogenic, mutagenic and/or reprotoxic properties.

[19] Here, the classification limit refers to the respective concentration in the final product that would lead to classification of the final product in accordance with the guidelines in Regulation (EC) No 1272/2008.

[20] Here, the classification limit refers to the respective concentration in the substance that would lead to classification of the substance in accordance with the guidelines in Regulation (EC) No 1272/2008.

Hazard statement according to the CLP Regulation		Limit Value [%] for substances[18] in the final product[19] *	Limit Value [%] for impurities in the substance[20]
Lact.	H362	0	≤ Classification limit
Acute Tox. 1	H300 (oral)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 1	H310 (dermal)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 1	H330 (inhal.)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 2	H300 (oral)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 2	H310 (dermal)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 2	H330 (inhal.)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 3	H301 (oral)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 3	H 311 (dermal)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 3	H331 (inhal.)	0	≤ Classification limit for **Acute Tox. 4**
Acute Tox. 4	H302 (oral)	**0.5** x Classification limit for Acute Tox. 4	—
Acute Tox. 4	H312 (dermal)	**0.5** x Classification limit for Acute Tox. 4	—
Acute Tox. 4	H332 (inhal.)	**0.5** x Classification limit for Acute Tox. 4	—
Asp. Tox. 1	H304	**0.5** x Classification limit for Asp. Tox. 1	—
STOT SE 1	H370	0	≤ Classification limit for **STOT SE 2**
STOT RE 1	H372	0	≤ Classification limit for **STOT RE 2**
STOT SE 2	H371	**0.5** x Classification limit for STOT SE 2	—
STOT RE 2	H373	**0.5** x Classification limit for STOT RE 2	—
STOT SE 3	H335	< Classification limit for STOT SE 3	—
STOT SE 3	H336	< Classification limit for STOT SE 3	—
Skin Corr. 1[A,B,C]	H314	< Classification limit for **Skin Irrit. 2**	—
Skin Irrit. 2	H315	< Classification limit for Skin Irrit. 2	—
Eye Dam. 1	H318	< Classification limit for **Eye Irrit. 2**	—
Eye Irrit. 2	H319	< Classification limit for Eye Irrit. 2	—
Resp. Sens. Category 1 and subcategories 1A and 1B	H334	< Classification limit for Resp. Sens. Category 1 and subcategories 1A and 1B	—
Skin Sens. Category 1 and subcategories 1A and 1B	H317	< Classification limit for Skin Sens. Category 1 and subcategories 1A and	—

Hazard statement according to the CLP Regulation		Limit Value [%] for substances[18] in the final product[19] *	Limit Value [%] for impurities in the substance[20]
		1B	
Aquatic Acute 1	H400	0	< Classification limit for Aquatic Acute 1
Aquatic Chronic 1	H410	0	≤ Classification limit for Aquatic Chronic 1
Aquatic Chronic 2	H411	< Classification limit for **Aquatic Chronic 3 and 4**	—
Aquatic Chronic 3	H412	< Classification limit for **Aquatic Chronic 3 and 4**	—
Aquatic Chronic 4	H413	< Classification limit **for Aquatic Chronic 3 and 4**	—

*** Compliance is required for all substances that are added and/or created in a concentration > 0.01 weight percent due to a chemical reaction in the lubricant used. It is irrelevant whether the added substance fulfils a function or is present as an impurity in the final product.**
The hazard statements not currently included in the EU Ecolabel are shown in red. Please take note that the hazard statements H318 and H335 were already included in Table 1 in TR 2.0.

In the Blue Angel approach depending of the concerns associated to the specific hazards and their categorization different concentration limits are allowed:

- Up to a **maximum of half of the relevant concentration** that would lead to **classification of the final product** in the specific hazard class.
- Up to a **maximum total concentration** that is smaller than the **concentration that would lead to classification of the final product** in the **specific hazard class**.
- Up to a **maximum total concentration** that is smaller than the **concentration that would lead to classification of the final product in the same hazard class but in a lower category**[21].

Moreover, additional information has been collected in order **to establish a prioritization among the hazard statements for which a higher degree of flexibility is needed**, according to Table 3.2. Following **indicators have been considered to select the degree of flexibility applicable to each hazard**:

- **Hazard groups**, i.e., prioritization based on the grouping of hazards as per the EU Ecolabel Chemicals Task Force[22]
- **% for each hazard statement** in assessed substances included in the **LuSC-list**
- **% for each hazard statement** in EU Ecolabelled **licenses**

Task Force document groups the hazard as following:

– **Group 1: Hazards subject to complete restriction**

[21] As example: Substances classified in the hazard classes "**Skin Corrosion 1A, 1B or 1C**" may only be added to the final product up to a maximum total concentration that is smaller than the concentration that would lead to classification in the hazard classes **"Skin Irritation 2**" in accordance with the guidelines in Regulation (EC) No 1272/2008 for the final product.

[22] Findings of the EU Ecolabel Chemicals Horizontal Task Force - Proposed approach to hazardous substance criteria development. 24th February 2014. Available online at: http://ec.europa.eu/environment/ecolabel/documents/Chemicals%20HTF_Approach%20paper.pdf

Substances present in mixtures, in an article or in any homogenous part of a complex article that meet the criteria of Article 57 of REACH regulation or that are identified according to the procedure described in Article 59 (1) of that Regulation. This group includes Category 1A and 1B CMR hazard classifications under CLP, endocrine disruptors, neurotoxins and sensitisers of 'equivalent concern'.

- **Group 2: Priority hazards for restriction to which stricter conditions shall apply**
  Hazards addressed include CMR Category 2, Category 1 and 2 acute toxins, Category 1 STOT, Category 1 allergens and Category 1 and 2 hazards to the aquatic environment.
  Substances that, in combination with these hazards, are also very persistent, persistent, very bioaccumulative or bioaccumulative, as defined according to Annex XIII of the REACH Regulation, shall be treated as Group 1 substances.
- **Group 3: Hazards to which greater flexibility may be applied**
  Hazards addressed include Category 3 and 4 hazards to the aquatic environment, Category 3 acute toxins and Category 2 STOT.
  Flexibility may be applied for instance if the fate of the product is not in the aquatic environment.

On the other hand, an analysis has been carried out in order to determine which percentage assessed substances included in the LuSC-list (either directly as substances or within the mixtures) and licenses is classified with of each hazard statement.

The data compiled was used as a weight of evidence to rank their impact and to take into account as indicators, in the proposal to limit values for the different hazards. The thresholds have been defined on the basis of the distribution of values obtained for the available assessed substances included in the LuSC-list and current licenses, so that they have been classified into low impact (green colour), medium impact (yellow colour) or high impact (red colour). See Table 3.4 and Table 3.5 for this assessment.

Table 3.4. Thresholds used to rank the impact on the LuSC-list and current licenses

INDICATORS FOR THE PRIORITIZATION OF FLEXIBILITY	Thresholds to rank the impact for each hazard statement
% for each hazard statement in assessed substances included in the LuSC-list (total)	Low 0-2%, Medium 3-8%, High >9%
% for each hazard statement in assessed substances included in Ecolabelled licenses	Low 0-2%, Medium 3-8%, High > 9%

The following table summarizes the results for the different indicators.

Table 3.5. Impact on the considered requirements on the LuSC-list and current licenses

Hazard categories present in the LuSC List and current licences		INDICATORS FOR THE PRIORITIZATION OF FLEXIBILITY		
		Prioritization of the hazard classes	% for each hazard statement in assessed substances included in the LuSC-list and their impact (total)	% for each hazard statement in assessed substances included in EU Ecolabelled licenses and their impact
Hazard Class and category	Hazard			

	Statement			
Repr. 2	H361f	GROUP 2	1%	0%
Repr. 2	H361d	GROUP 2	1%	0%
Asp.Tox. 1	H304	GROUP 2	1%	7%
Acute Tox. 3	H301	GROUP 3	0%	2%
Acute Tox. 3	H311		0%	2%
Acute Tox. 3	H331		0%	2%
STOT RE. 1	H372	GROUP 2	0%	1%
STOT RE. 2	H373	GROUP 3	3%	2%
STOT SE. 3	H336	-	0%	1%
Skin Sens. Category 1 and subcategories 1A and 1B	H317	GROUP 2	3%	6%
Skin Corr. 1[A,B,C]	H314	-	2%	1%
Skin Irrit. 2	H315	-	17%	16%
Eye Dam.1	H318	-	10%	4%
Eye Irrit. 2	H319	-	18%	12%
Aquatic Acute 1	H400	GROUP 2	11%	5%
Aquatic Chronic 1	H410	GROUP 2	5%	3%
Aquatic Chronic 2	H411	GROUP 2	7%	11%
Aquatic Chronic 3	H412	GROUP 3	8%	13%
Aquatic Chronic 4	H413		13%	11%
Repeated exposure may cause skin dryness or cracking	EUH066	-	0%	1%

For the **third draft proposal**, a higher degree of flexibility for those hazards statements that are present in the existing LuSC-list substances and in the current EU Ecolabel licences has been considered. Based on the above-explained analysis the following thresholds have been proposed:

- For substances included in **Group 3**: **Maximum total concentration that is smaller than the concentration that would lead to classification of the final product**, as in the existing criteria in force.
- For substances included in **Group 2 and with medium/high impact on LuSC-list/ current licenses**: **maximum of half of the relevant concentration that would lead to classification of the final product** with the specific hazard class.
- For substances included in **Group 2 and with low impact on LuSC-list and current licenses**: Concentration limit < 0.010 % weight by weight per substance in the final product according to the horizontal approach for other product groups.

Table 3.6 shows the limits proposed for the revised EU Ecolabel criteria in comparison with the current Blue Angel criteria and the impact of the third proposal on the current licences and LuSC list substances, estimated based on the data provided in the consultation process.

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Table 3.6. Comparison between the current Blue Angel limits and the proposed limits (%) for the EU Ecolabel

Hazard Class and category	Hazard Statement	Proposal Limit	Blue Angel Limit Value [%] for substances in the final product[23]	Prioritization of the hazard classes	Impact on the LuSC-list	Impact on EU Ecolabelled licenses
Repr. 2	H361f Suspected of damaging fertility	< 0.010 % weight by weight per substance in the final product	0	GROUP 2	LOW	LOW
Repr. 2	H361d Suspected of damaging the unborn child	< 0.010 % weight by weight per substance in the final product	0	GROUP 2	LOW	LOW
Asp.Tox. 1	H304 May be fatal if swallowed and enters airways	0.5 x Classification limit final product	0.5 x Classification limit[3] for Asp. Tox. 1	GROUP 2	LOW	MEDIUM
Acute Tox. 3	H301 Toxic if swallowed	< Classification limit final product	0	GROUP 3	LOW	LOW
Acute Tox. 3	H311 Toxic in contact with skin				LOW	LOW
Acute Tox. 3	H331 Toxic if inhaled				LOW	LOW
STOT RE. 1	H372 Causes damage to organs through prolonged or repeated exposure	< 0.010 % weight by weight per substance in the final product	0	GROUP 2	LOW	LOW
STOT RE. 2	H373 May cause damage to organs through prolonged or repeated exposure	< Classification limit final product	0.5 x Classification limit for STOT RE 2	GROUP 3	MEDIUM	LOW
STOT SE. 3	H336 May cause drowsiness or dizziness	< Classification limit final product	< Classification limit for STOT SE 3	-	LOW	LOW
Skin Sens. Category 1 and subcategories 1A and 1B	H317: May cause allergic skin reaction	0.5 x Classification limit final product	< Classification limit for Skin Sens. Category 1 and subcategories 1A and 1B	GROUP 2	MEDIUM	MEDIUM
Skin Corr. 1[A,B,C]	H314 Causes severe skin burns and eye damage	< Classification limit final product	< Classification limit for Skin Irrit. 2	-	LOW	LOW
Skin Irrit. 2	H315 Causes skin irritation	< Classification limit final product	< Classification limit for Skin Irrit. 2	-	HIGH	HIGH
Eye Dam.1	H318: Causes serious eye damage	< Classification limit final product	< Classification limit for Eye Irrit. 2	-	HIGH	MEDIUM
Eye Irrit. 2	H319 Causes serious eye irritation	< Classification limit final product	< Classification limit for Eye Irrit. 2	-	HIGH	HIGH
Aquatic Acute 1	H400 Very toxic to aquatic life	0.5 x Classification limit final product	0	GROUP 2	HIGH	MEDIUM
Aquatic Chronic 1	H410 Very toxic to aquatic life with long-lasting effects	< Final product classification limit for H412 and H413	0	GROUP 2	MEDIUM	MEDIUM
Aquatic Chronic 2	H411 Toxic to aquatic life with long-lasting effects		< Classification limit for Aquatic Chronic 3 and 4	GROUP 2	MEDIUM	HIGH
Aquatic Chronic 3	H412 Harmful to aquatic life with long-lasting effects			GROUP 3	MEDIUM	HIGH
Aquatic Chronic 4	H413 May cause long-lasting effects to aquatic life				HIGH	HIGH
Repeated exposure may cause skin dryness or cracking	EUH066 Repeated exposure may cause skin dryness or cracking	< Classification limit final product	-	-	LOW	LOW

[23] Applies to substances present above 0.01% in the final product

Requirement 1 (b) Specified restricted substances

No changes have been introduced in the requirement 1 (b) Specified restricted substances when compared with the version in the TR 2.0.

Requirement 1 (c) Substances of very high concern (SVHCs)

In this case (absolute restriction), the problem would be the limit of detection of the techniques used to determine the presence of these SVHCs. Nowadays, there are 174 SVHC included in the candidate list, and depending on each substance the technique is different. In a general way, if we consider as an example HPLC (High-performance liquid chromatography), a good resolution could be ppb (one part per billion). This is equivalent to 0,0001%. From an analytical (and chemical) point of view it is very difficult to conclude the absolute "0%". According to this, the limit value has been maintained to 0.01%. This is in line with revised criterion 1 (b) (Specified restricted substances) where the limit is set to 0.01%.

Moreover, the total restriction is not an easily verifiable parameter due to the absence of information below 0.01%. Consequently the current existing threshold in force has been maintained.

- **Outcomes from last written consultation, Inter Service Consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this criterion as a result of the final consultation:

- The threshold for H317 has been changed to final product classification in Requirement 1 (a) Hazardous substances (ii) substances,
- The threshold for H410 has been amended to align to the ambition level set in criterion 2.
- The sentence regarding impurities and related required compliance with criterion 1 has been reformulated as follows: *For the purpose of criterion 1 impurities stated in the SDS, which presence in the final product equals or exceeds 0.010% in the final product, shall comply with the same requirements as the intentionally added substances.* This is in line with Blue Angel: Compliance is required for all substances that are added and/or created in a concentration > 0.01 weight percent due to a chemical reaction in the lubricant used. It is irrelevant whether the added substance fulfils a function or is present as an impurity in the final product.
- Wording has been modified to make the criteria text and the table more coherent.

Rationale of proposed "assessment and verification"

With regards to the first proposal for the **assessment and verification**, the text for each of the sub-requirements was aligned to the recently voted detergents product group.

During the 2nd AHWG meeting, it was suggested that the verification and assessment should be indicated in the text in a clearly and verifiable way in order to facilitate a common approach for all CBs. The text may be modified subject to further discussions on the final formulation of this criterion; nevertheless, changes have been introduced for the third proposal in order to clarify the text and to specify the evidence that needs to be provided in order to comply with each of the sub-requirements.

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Only minor wording changes have been introduced in the assessment and verification text as a result of the final consultation. This is however no content-wise change, just clarification of the wording following the comments provided.

3.2 CRITERION 2: Additional aquatic toxicity

Final proposal for criterion 2: Additional aquatic toxicity

The applicant shall demonstrate compliance by meeting the requirements of either criterion 2.1 or 2.2.

2.1. Requirement for the lubricant and its main components

The critical concentration for the aquatic toxicity for both the freshly prepared lubricant and for each main component shall not be lower than the values specified in Table 2.

Main component means any substance accounting for more than 5% by weight of the lubricant.

Table 2. Aquatic toxicity values for both freshly prepared lubricant and for each main component

		ALL	PLL	TLL
Aquatic toxicity for the freshly prepared lubricant	Critical concentration for acute aquatic toxicity OR	>100 mg/L	>1000 mg/L	>1000 mg/L
	Chronic aquatic toxicity	>10 mg/L	>100 mg/L	>100 mg/L
Aquatic toxicity for each main component	Critical concentration for acute aquatic toxicity OR	>100 mg/L		
	Chronic aquatic toxicity	> 10 mg/L		

Available acute aquatic toxicity test data for each main component shall be provided on each of the following two trophic levels:

- crustacean (daphnia preferred),
- aquatic plants (algae preferred).

In case acute aquatic toxicity test data is missing in one or both trophic levels, available test data on chronic aquatic toxicity for both the crustacean (daphnia preferred) and fish trophic level shall be accepted.

QSARs could be used to fill data gaps for chronic toxicity or for acute toxicity in only one of the relevant trophic levels.

In case the aforementioned test data is not available for each main component, a test shall be performed to generate data for acute toxicity in the missing trophic level/s (i.e crustacean and/or aquatic plants).

Available acute aquatic toxicity test data for the lubricant shall be provided on each of the following three trophic levels:

- crustacean (daphnia preferred),

- aquatic plants (algae preferred),
- fish.

In case acute aquatic toxicity test data for the applied lubricant is missing for any of the mentioned trophic levels available test data on chronic aquatic toxicity shall be accepted for the missing trophic level/s.
In case the above data is not available for the applied lubricant, a test shall be performed to generate data on acute aquatic toxicity for the missing trophic level/s.

2.2. Requirement for each intentionally added or formed substances at or above 0,10 % weight by weight in the final product

Substances exhibiting a certain degree of aquatic toxicity are allowed up to a cumulative mass concentration indicated in Table 3.

Table 3. Cumulative mass percentage (%w/w) limits for substances present in the product with respect to their aquatic toxicity

	Cumulative mass percentage (% weight by weight in the final product)		
	ALL	**PLL**	**TLL**
Acute aquatic toxicity **>100 mg/L** or Chronic aquatic toxicity > **10 mg/L**	**Not limited**		
Acute aquatic toxicity **>10 to ≤ 100 mg/L** or **1 mg/L** < Chronic aquatic toxicity **≤ 10 mg/L**	≤ 10 (≤ 20 for ALL greases)	≤ 10 (≤ 15 for PLL greases)	≤ 2 (≤ 10 for TLL greases)
Acute aquatic toxicity **>1 to ≤ 10 mg/L** or **0,1 mg/L** < Chronic aquatic toxicity **≤ 1 mg/L**	**≤ 2,5** (≤ 1 for ALL greases)	**≤ 0,6**	**≤ 0,4**
Acute aquatic toxicity**≤ 1 mg/L** or Chronic aquatic toxicity **≤ 0,1 mg/L**	**≤ 0,1/M (*)**	**≤ 0,1/M (*)**	**≤ 0,1/M (*)**

(*) M-factors for highly toxic components of mixtures shall be applied in accordance with Article 10 of Regulation (EC) No 1272/2008([13]) as described in section 4.1.3.5.5.5 of Annex I to that Regulation.

Available chronic aquatic toxicity test data for each substance (each intentionally added or formed substances at or above 0,10 % weight by weight in the final product) shall be provided for each of the following two trophic levels:

- crustacean (daphnia preferred),
- and fish

In case chronic aquatic toxicity test data is missing in one or both trophic levels, available data on acute aquatic toxicity for both trophic levels, crustacean (daphnia preferred) and aquatic plants (algae preferred) shall be accepted.
QSARs could be used to fill data gaps for chronic toxicity or for acute toxicity in only one of the relevant trophic levels.
In case the above data is not available for each substance, a test shall be performed to generate data for acute toxicity in the missing trophic level/s (i.e crustacean and/or aquatic plants).
Assessment and verification applicable to criteria 2.1 and 2.2: In case of self-assessment by the applicant, for each substance, main component or for the lubricant, the applicant shall provide test reports or literature data including the references demonstrating compliance with the requirements set in sub-criteria 2.1 or 2.2.
For each substance or main component where the assessment is based on a valid letter of compliance (LoC), a copy of the letter shall be provided. For each substance or main component selected from the Lubricant Substance Classification list (LuSC-list) the assessment can be based on the information reported in said list and no documents need to be

submitted.
Either marine or freshwater toxicity data are accepted.

Acute aquatic toxicity data (available or generated for the application) shall originate from tests carried out according to:

- ISO 10253 or ISO 8692 or OECD Test Guideline 201 or Part C.3 of the Annex to Regulation (EC) No 440/2008([24]) for algae,
- ISO 6341 or OECD Test Guideline 202 or Part C.2 of the Annex to Regulation (EC) No 440/2008([24]) for daphnia.
- ISO 7346 or OECD Test Guideline 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008([24]) for fish (only applies to available existing data).
- fish embryo toxicity (FET) (non-animal alternative) test according to OECD Test Guideline 236 or part C.49 of the Annex to Regulation (EC) No 440/2008([24]) for fish (only applies when a test needs to be performed for the application).

Only acute aquatic toxicity (72 or 96 hr) ErC_{50} for algae, (48hr) EC_{50} for daphnia and (96hr) LC_{50} for fish are accepted.
Chronic aquatic toxicity data (available) shall originate from tests carried out according to:

- ISO 10253 or ISO 8692 or OECD Test Guideline 201 or Part C.3 of the Annex to Council Regulation (EC) No 440/2008([24]) for algae.
- Part C.20 of the Annex to Regulation (EC) No 440/2008([24]) or OECD Test Guideline 211 for daphnia,
- OECD Test Guideline 215 or Part C.14 of the Annex to Regulation (EC) No 440/2008([24]) or ISO 12890 or OECD Test Guideline 212 or part C.15 of the Annex to Regulation (EC) No 440/2008([24]) or OECD Test Guideline 210 for fish.

Only chronic toxicity data in the form of No Observed Effect Concentration (NOEC) data shall be accepted.
When QSARs are used to fill data gaps, the applicant shall provide the prediction generated for the target chemical. Results of (Q)SARs shall only be accepted if documentation on the validity and applicability domain of the applied model is provided by the applicant.
In the case of slightly soluble substances or mixtures (<10 mg/L) the method of the water-accommodated fraction (WAF) can be used in the aquatic toxicity determination. The established loading level referred to as LL50 and related to the lethal loading or the EL50 related to the effective loading for acute aquatic toxicity and NOELR related to the no observable effect loading rate for chronic aquatic toxicity may be used directly in the classification criteria. The preparation of a water-accommodated fraction shall follow the recommendations set out according to one of the following guidelines: Appendix C to ECETOC Technical Report No 26 (1996), OECD 2002 Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (OECD Series on Testing and Assessment, No. 23), ISO 5667-16 Water quality - Sampling - Part 16 (Guidance on biotesting of samples) , ASTM D6081-98 (Standard practice for Aquatic Toxicity Testing for Lubricants: Sample Preparation and Results Interpretation) or equivalent methods. In addition, demonstration of the absence of toxicity for a substance at its limit of water solubility shall be deemed to have met the requirements of this criterion.

The following substances are exempted from requirements 2.1 and 2.2:

- any substance which is unlikely to cross biological membranes MM > 800 g/mol and with a molecular diameter > 1,5 nm (> 15 Å), or
- any substance which is a polymer and whose molecular weight fraction

[24] Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p 1).

below 1 000 g/mol is less than 1 %, or

- any substance which is highly insoluble in water (water solubility < 10 µg/l)

The water solubility of substances shall be determined where appropriate according to OECD Test Guideline 105 or Part A.6 of the Annex to Regulation (EC) No 440/2008([24]) or equivalent test methods.

A polymer molecular weight fraction below 1000 g/mol shall be determined according to Part A.19 of the Annex to Regulation (EC) No 440/2008([24]) or OECD Test Guideline 119 or equivalent test methods.

Rationale of the proposed criterion text

According to the technical analysis lubricants have potential to cause disturbances in aquatic ecosystems when they cause emissions to water during their life cycle or due to accidental spillages. The aim of the existing criteria in force (i.e. *3. Additional aquatic toxicity requirements)* is to limit the aquatic toxicity of the ingredients used in lubricant product group. In the **first revised proposal**, the criterion was suggested to be kept, however thresholds were revised considering the existing EU Ecolabel licences. In order to decrease the animal tests it was suggested to maintain existing criterion 3.1 (requirements for the product and main components) only for greases when unknown substances are present in the mixture (up to 5% by weight in the lubricant) or reliable aquatic toxicity data of the mixture exists. For other lubricants categories (and when adequate toxicity data are available for greases components) it was suggested to apply requirement 2.2 (existing 3.2). In addition, in the first revised proposal it was suggested to align to section 4.1 of Annex I to CLP Regulation and to request the toxicity data for three trophic levels.

In the **second proposal**, categories 1 and 5 were unified as ALL, category 3 as TLL and categories 2 and 4 as PLL considering the revised scope proposal. This did not, however, implied any additional modification since the thresholds for the merged categories were the same. Based on some barriers identified during the first consultation, in the second proposal it was proposed to maintain the option of testing the lubricant and its main components (criterion 2.1) for all categories because the full set of aquatic data will probably not be available for every ingredient for all categories and not only for greases, as suggested in the first proposal.

In relation to thresholds for criterion 2.1, the values were kept as the existing values in force at the AHWG1.

With regards to the criterion 2.2, data provided by Competent Bodies for 149 currently EU Ecolabelled products from 11 different countries was analysed during the revision process. This **represents approximately the 40% of the total EEL products available on the market**. In the second revised proposal threshold values were amended based on the analysis of this additional data.

Most of the thresholds are suggested to be maintained as in the first proposal as the new data revealed minor impact on EU Ecolabel products. However some minor modifications were introduced to reflect the results of the analysis:

- Threshold values for category ALL have been maintained as presented in the TR1.0. Only 3 of existing assessed licenses would not be able to comply with the revised thresholds (2 for category 1 and 5 (chronic hazard category 2) and 1 for category 5 (Chronic hazard category 3)).
- Threshold values on chronic hazard category 2 for category PLL have been relaxed compared to the first proposal from a cumulative mass percentage equal to or less

than ≤ 0,5% to ≤ 0,6%. In this case, all the assessed licences would be able to comply with the revised thresholds.

- Finally, threshold values on chronic hazard category 2 for category TLL have also been relaxed compared to the first proposal from a cumulative mass percentage equal to or less than ≤ 0,3% to ≤ 0,4%. Only 3 of existing assessed licenses would not be able to comply with the revised thresholds.

The comparison of the new revised and the existing thresholds in force are given in Table 3.7. Comparison with the existing criteria in force shows that the ambition level has been considerably increased.

Table 3.7. Criterion 2.2 Proposed threshold values for the aquatic toxicity, existing limits and number of products affected (out of 149 products)

Aquatic toxicity		Cumulative mass percentages (%w/w) of substances present within the candidate lubricant)								
		CATEGORY 1 AND 5 (ALL)			CATEGORY 2 AND 4 (PLL)			CATEGORY 3 (TLL)		
		Current limit	Revised proposed limit	EU ecolabelled products affected	Current limit	Revised proposed limit	EU ecolabelled products affected	Current limit	Revised proposed limit	EU ecolabelled products affected
Not hazardous to the aquatic environment	Acute aquatic toxicity **>100 mg/L** or Chronic aquatic toxicity>**10 mg/L**	NOT LIMITED								
Chronic hazard category 3	Acute aquatic toxicity **>10 to ≤ 100 mg/L** or **1 mg/L** < Chronic aquatic toxicity **≤ 10 mg/L**	≤ 20	**≤ 10**	1	≤ 25	**≤ 20**	0	≤ 5	**≤ 2**	0
Chronic hazard category 2	Acute aquatic toxicity **>1 to ≤ 10 mg/L** or **0,1 mg/L** < Chronic aquatic toxicity **≤ 1 mg/L**	≤ 5	**≤ 2,5**	2	≤ 1	**≤ 0,6**	0	≤ 0,5	**≤ 0,4**	3
Chronic category 1 / **Acute category 1**	Acute aquatic toxicity**≤ 1 mg/L** or Chronic aquatic toxicity **≤ 0,1 mg/L**	≤ 0,1/M/ ≤ 1/M	**≤ 0,1/M**	0	≤ 0,1/M	**≤ 0,1/M**	0	≤ 0,1/M	**≤ 0,1/M**	0

Moreover, in the second proposal, in order to reduce the number of tests on animals, as requested by stakeholders, it was proposed to keep the number of trophic level testing as it is in the **existing EU Ecolabel decision**, i.e. for the following two trophic levels: fish and crustacean.

- **Outcomes from and after the 2nd AHWG meeting**

Main comments received from stakeholders during and after the 2nd AHWG meeting are summarized below:

- Concerning the proposed stricter thresholds values for criterion 2.2, stakeholders noted that they would cause loss of some licenses.
- One stakeholder mentioned that the proposal underestimates the environmental impact of MWFs due to the surfactants used in their formulation as the most sensitive trophic level for surfactants is the fish.

- There was disagreement among the stakeholders on the selection of the trophic levels for acute and chronic aquatic toxicity data accepted for the assessment and verification.
- A stakeholder mentioned the possibility to use NOEC algae as chronic aquatic toxicity data instead of fish with the aim not to perform animal tests with vertebrates (fish) for the purpose of ecolabelling.

- **Further research and main changes in third proposal**

Against this background, the additional work after the second consultation has been focused on the issues addressed in the comments provided.

Concerning the proposed thresholds limit values for criterion 2.2, where stakeholders mentioned that they would cause loss of some licenses which would not comply with these revised limits, it was seen that the impact of the revised thresholds is minor, This was confirmed by the analysis of data provided on aquatic toxicity of 143 EU ecolabelled products from 11 countries.

One stakeholder commented that in the case of greases, if the threshold values for the aquatic toxicity regarding the content of harmful substances decrease from 25% to 20%, complex greases will not be able to comply due to the content of soaps. It was proposed to decrease the allowed toxic content in the greases formulation, but not the content of harmful substances. Based on data provided by the Competent Bodies on existing EEL products and in the specific case of greases, it should be noted that according to Table 3.3 on page 39 of the TR2.0, the **range** of cumulative mass percentage **(%w/w) of harmful (E) substances** present within the lubricant was between: **0-18,49 (average=7,51; 50th percentile= 5,05 and 75th percentile= 13,02)**. According to the evaluation of the existing products, **all the assessed licenses would be able to comply with the revised thresholds for category PLL**.

Regarding other threshold values, data provided by the competent bodies and stakeholders has been revised again, with special attention to the concerns of stakeholders due to the categorization of greases under TLL and the loss of licenses. Data from 25 greases certified (or aiming to apply for the label) was received during the process revision. 20% of them have a threshold value ≤ 2% (chronic aquatic hazard category 3), 92% of them have a threshold value ≤ 0,4% (chronic aquatic hazard category 2) and 100% have a threshold value ≤ 0,1/M % (acute/chronic aquatic hazard category 1) as indicated in the below table.

Table 3.8. Criterion 2.2 Proposed threshold values for the aquatic toxicity and number of products that would pass these revised limits for greases

		REVISED Cumulative mass percentage (% weight by weight in the final product)	**Percentage of products that would pass the revised limits for greases under TLL**
		TLL	
Substance classified as chronic aquatic hazard category 3 according to CLP	Acute aquatic toxicity **>10 to ≤ 100 mg/L** or **1 mg/L** < Chronic aquatic toxicity **≤ 10 mg/L**	≤ 2	20%
Substance classified as chronic aquatic hazard category 2 according to CLP	Acute aquatic toxicity **>1 to ≤ 10 mg/L** or **0,1 mg/L** < Chronic aquatic toxicity **≤ 1 mg/L**	**≤ 0,4**	92%
Substance classified as	Acute aquatic toxicity**≤ 1**	**≤ 0,1/M**	

		REVISED Cumulative mass percentage (% weight by weight in the final product) TLL	Percentage of products that would pass the revised limits for greases under TLL
chronic aquatic hazard category 1 according to CLP	**mg/L** or Chronic aquatic toxicity ≤ **0,1 mg/L**		100%
Substance classified as acute aquatic hazard category 1 according to CLP			

No extra specific data about distribution of greases depending on the environmental release has been received, thus it is not exactly known which % of this 25 greases certified are currently PLL or TLL. Therefore, according the precautionary approach and considering that there are currently certified greases able to comply with TLL these aquatic toxicity values, it has been proposed to maintain the limits defined in the second draft.

With regards to the stakeholder´s comment that the current assessment underestimates the environmental impact of MWFs due to the most sensitive trophic specie for the surfactants (applied in large quantities in MWFs) is fish, some scientific articles have been revised with the aim to analyse which is the most sensitive trophic specie for surfactants. Based on that, it has been found that the toxicity of the most common classes of surfactants (anionic, cationic and non-ionic) to various organisms is well documented. In a study[25] of anionic sodium dodecyl sulphate (SDS) toxicity including different species of algae, crustaceans and fish, the algae proved to be the most sensitive (EC50 mgL-1 36,58; 41,04 and 40,15 respectively). The same occurred for the anionic linear alkylbenzene sulphonic acid (LAS) (EC50 mgL-1 3,5; 5,96 and 5,1 respectively) , alkyl ethoxysulphate (AES) (EC50 mgL-1 2,18-3,5; 23,92 and 10,84 respectively) and the nonionic alcohol ethoxylate (AE) (EC50 mgL-1 0,101-0,140; 0,39 and 4,35 respectively) where the algae was the most sensitive species. For the cationic quaternary ammonium compound (QAC) the crustaceans (Daphnia Magna) proved to be the most sensitive species (EC50 mgL-1 0,79; 0,38 and 1,21 respectively). The study indicates that the toxicity of a single surfactant is highly specific, not only for the type and class of surfactant, but also for the organism tested. In conclusion, any generalization or application to similar organisms cannot be made.

In addition, as **different organisms have different sensitivity to the toxics, it should be necessary to evaluate the most appropriate organism in order to establish the maximum permissible concentrations in aquatic ecosystems (lowest toxic value)** [26]. Against this background, it was initially proposed in the TR1.0 that the aquatic toxicity test results were provided for all the three trophic levels and then selects the lowest toxic value based on the more sensitive organism.

Nevertheless this proposal was rejected as this would increase the testing and majority of stakeholders opposed to the initial proposal. In the second draft and according to the

[25] Surfactants in the environment. Tomislav Ivankovic and Jasna Hrenovic. Division of Biology, Faculty of Science, University of Zagreb, Zagreb, Croatia. January 2009.

[26] Acute toxicity of anionic and non-ionic surfactants to aquatic organisms. Lechuga M, Fernández-Serrano M, Jurado E, Núñez-Olea J, Ríos F.

stakeholder´s comments it was proposed to **request data for the same trophic levels according to REACH for the registration of substances and as in the current EU Ecolabel**.

A simplified list of the standard information requirements is given below for the different tonnage bands in which the registrant manufacturers or imports the substance according to REACH information requirements (Annexes VII to X).

Table 3.9. List of standard information requirements for the different tonnage bands according to REACH (Annexes VII to X)

Information required for standard registration of ≥ 1 tonnes a year (Annexes VII and VIII of REACH)		**Information required for standard registration of ≥ 10 tonnes a year (Annexes VII and VIII of REACH)**		**Information required for standard registration of ≥100 tonnes a year (Annex IX of REACH)**		**Information required for standard registration of ≥1000 tonnes a year (Annex X of REACH)**	
Non-vertebrate animal endpoints	Vertebrate animal endpoints	Non-vertebrate animal endpoints	Vertebrate animal endpoints	Non-vertebrate animal endpoints	Vertebrate animal endpoints	Non-vertebrate animal endpoints	Vertebrate animal endpoints
Short-term toxicity on invertebrates (preferred species *Daphnia)*			Short- term toxicity on fish (the registrant may consider long-term toxicity testing instead of short- term)	Long-term toxicity testing on invertebrates (preferred species Daphnia)	Long-term toxicity testing on fish (Fish early-life stage (FELS) toxicity test or Fish short-term toxicity test on embryo and sac-fry stages or Fish, juvenile growth test)	Terrestrial organisms (Soil compartment)	
Growth inhibition study aquatic plants (algae preferred)							

In conclusion, it should be noted that in the second proposal the trophic levels were reverted to those included in the existing text in force and in line with REACH requirements annexes VII to IX.

Moreover, a summary of the Blue Angel approach for Biodegradable Lubricants and Hydraulic Fluids (RAL-UZ178) related to the data that must be submitted by the applicant for each of the different trophic levels for components or the final product has been provided according to the table below.

Table 3.10. Summary of the Blue Angel approach (RAL-UZ178) related to the data that must be submitted by the applicant for each of the different trophic levels for components or the final product

The applicant shall comply with the requirements in either Paragraph 3.3.1 or 3.3.2	
3.3.1Requirements for components	**3.3.2Requirements for the final product**

If data is submitted about the components[27], it must comply with the following criteria: - Chronic aquatic toxicity data (NOEC) must be submitted for each of the two trophic levels: daphnia and fish - If no NOEC is available, the acute test data for each of the three trophic levels: algae, daphnia and fish can be used. NOTE: Data need only be submitted for components ≥0,1% weight in the final product with the condition that an upper limit of 0,5% weight of non-evaluated substances may not be exceed.	In terms of the acute or chronic aquatic toxicity of the final product, additional test data is to be submitted for algae, daphnia and fish. Verification is to be provided in the form of one test for each of the three trophic levels. Note: Only permissible acute tests for algae are considered (ISO/DIS 10253 and OECD 201 or Part C.3 of the Annex to Regulation (EC) No. 440/2008) and not for chronic.

As in the current EU Ecolabel a fraction of the product below 0,5% (w/w) not assessed for aquatic toxicity is allowed. Nevertheless in the Blue Angel approach the requirement for the main components, understood as any substances accounting for more than 5% (w/w) in the lubricant, is not considered. Thus, only requirements for components, understood as each stated substances present above 0,10% (w/w), or lubricant (final product) are considered. In the case of the substances present at a concentration equal to or above 0,10% (w/w), chronic aquatic toxicity data must be submitted for daphnia and fish (as in the EU Ecolabel), nevertheless if chronic data is missing, acute test data for all the three trophic levels must be provided by the applicant.

With regards to the final product (lubricant), acute or chronic aquatic toxicity data must be submitted for all the three trophic levels. As in Blue Angel, the EU Ecolabel follows the same approach, i.e., acute toxicity data for the applied lubricant must be provided for all the three trophic levels, but in case acute data is missing, available existing chronic aquatic toxicity data shall be accepted for each of the above-mentioned three trophic levels.

Finally, with regards to the stakeholder´s comment to consider the possibility to use NOEC algae as chronic aquatic toxicity data instead of fish with the aim to limit the use of animal tests with vertebrates (fish), **it should be noted that even the aquatic plant growth inhibition tests (ErC_{50}) are normally considered as chronic tests, the EC_{50} s are treated as acute values for classification purposes.** With the aim not to perform animal tests with vertebrates (fish) for the purpose of the EU Ecolabelling, only acute aquatic toxicity tests shall be accepted for daphnia and algae. Moreover, for the applied lubricant, the fish embryo toxicity test (FET) (as non-animal alternative) shall be accepted, when new test need to be performed for the application.

In summary, based on the comments received during and after the 2nd AHWG meeting and further research carried out, main changes and conclusions for the third proposal are summarized below:

- In general, the text has been revised to define better which data should be submitted and when the tests would need to be performed in order to generate new data.
- The proposed thresholds limit values for criterion 2.2 have been maintained as proposed in TR 2.0.
- No changes in the trophic levels data required have been introduced. The existing text in force since second criteria proposal (TR2.0) is maintained.

- In order to limit use of animal tests with vertebrates (fish):
    - OECD Test Guideline 236 or part C.49 of the Annex to Regulation (EC) No 440/2008 (**fish embryo toxicity (FET)) when fish acute aquatic toxicity data need to be generated for the applied lubricant** is included**.** See explanation below in the rationale of the proposed assessment and verification.
    - **Tests with vertebrates (fish)** for the applied lubricant shall only be accepted in the case of available data on **acute aquatic toxicity.**
    - For each main component and intentionally added or formed substances at or above 0,10%, in case data on **chronic and acute aquatic toxicity is** missing, **only acute aquatic toxicity test shall be accepted for each of the following two trophic levels:** crustacean (**daphnia** preferred) and aquatic plants (**algae** preferred).

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this criterion as a result of the final consultation:

- Values for cumulative mass percentage limit on chromic aquatic hazard cat. 3 substances (requirement 2.2) have been modified according to stakeholders input and data gathered during the revision. The values for greases have been relaxed considering that the maximum value on harmful substances for existing grease licences is 18%. Considering the proposed amendment, about 50 % of certified greases would comply with the relaxed TLL value for greases (10%) and approx. 80% would comply with PLL value for greases (15%).
- In addition, considering that specific values for greases are proposed, the general value for PLL on chronic aquatic hazard cat.3 cumulative mass percentage have been made slightly more stringent. The merging of categories 2 (greases) and 4 under PLL resulted in high value due to the fact that current licences for greases present very high values compared to licenses of lubricants under category 4. Revised proposal follows a more logical pattern with regards the potential release and associated concern for the different sub-groups.

Rationale of proposed "assessment and verification"

With regard to the first and second proposal for the assessment and verification it was suggested to accept QSARs to fill data gap in only one of the trophic levels rather than having to perform a test.

- **Outcomes from and after the 2nd AHWG meeting**

Main comments received from stakeholders during and after the 2nd AHWG meeting with regards to the assessment and verification section are summarized below:

- Proposal of alignment between *OECD Guidelines for the testing of chemicals* (OECD Test Guidelines) and corresponding standards of the *International Organisation for Standardization* (ISO) in the area of environmental effects (toxicity to aquatic organisms).
- Proposal to add the fish embryo toxicity (FET) test according to OECD 236 as a non-animal alternative to the acute fish toxicity test. No animal tests with vertebrates (fish)

should be performed for the purpose of ecolabelling and only available existing fish toxicity data should be used.

- Proposal to delete the recommended guidelines for the preparation of a water-accommodated fraction since they refer to the addition of poorly soluble substances to biodegradation tests, but not to the preparation of WAFs for ecotoxicity testing. Relevant standards and guidelines for the WAF preparation have been proposed.
- Proposal to include a clarification on what models must be used when introducing (Q)SARs, what error is allowed in their prediction and how high the similarity coefficient must be.

Additional work after the second consultation has been focused on the issues addressed in the above-mentioned comments.

In relation to the use of (Q)SARs, it should be noted that structure-activity relationship (SAR) and quantitative structure-activity relationship (QSAR) models - collectively referred to as (Q)SARs – are mathematical models that can be used to predict the physicochemical, biological and environmental fate properties of compounds from the knowledge of their chemical structure. These models are available for free or as commercial software and (Q)SAR predictions can support results from tests that have not been performed, in order to fulfil the information requirements for REACH registration dossier. According to this, results of (Q)SARs may be used instead of testing when the conditions set in REACH Annex XI (1.3) are met:

i. Scientific validity of the (Q)SAR model;
ii. The substance should fall within the applicability domain of the (Q)SAR model;
iii. The prediction should be fit for the regulatory purpose; and
iv. The information should be well documented

According to ECHA Guidance[28], the recommended strategy for using (Q)SARs is to run all (Q)SAR models available for the endpoint to be fulfilled, especially when models are independent from each other (e.g. the algorithms are based on different descriptors, structural alerts or training sets). Agreement among predictions generated from independent and scientifically-valid (Q)SAR models increases the confidence in relying on the predictions. If the valid predictions show small quantitative differences, **the most conservative result should be chosen.**

According to the stakeholder´s comment, it should be noted that in general, different (Q)SARs might perform better depending on the type of chemicals and endpoint under evaluation, thus it is not deemed necessary to identify which should be these (Q)SARs. Instead, a pragmatic solution could be to ask the applicant to present data from available and valid (Q)SARs (as explained in section 3 of ECHA Guidance – *Practical guide how to use and report (Q)SARs*) models and to take the lowest one . A non-exhaustive list of (Q)SAR programs available for ecotoxicological endpoints are summarized below[29].

Endpoint	Software tool	Models/Modules	Free or commercial

[28] More information available online at ECHA Guidance – *Practical guide how to use and report (Q)SARs:* https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf/407dff11-aa4a-4eef-a1ce-9300f8460099

[29] However, it constitutes neither an exhaustive list of available programs nor a list of regulatory validated QSAR models.

Short-term toxicity to fish	**Danish QSAR Database (DTU)**	**Fathead minnow 96h LC50 from DTU**	**Free**
	ECOSAR (US EPA)	**Fish, 96-hr, LC50**	**Free**
	T.E.S.T. (US EPA)	**Fathead minnow LC50 (96 hr)**	**Free**
	VEGA (IRFMN)	**SarPy/IRFMN classification and KNN/Read-Across model**	**Free**
	ADMET Predictor (Simulations Plus)	**Toxicity module**	**Commercial**
	CASE Ultra (MultiCASE)	**EcoTox model bundle**	**Commercial**
	Discovery Studio (Accelrys)	**Fathead Minnow LC50**	**Commercial**
Long-term toxicity to fish	**ECOSAR (US EPA)**	**Fish, ChV**	**Free**
Short-term toxicity to aquatic invertebrates (daphnia)	**Danish QSAR Database (DTU)**	**Daphnia magna 48h EC50 from DTU**	**Free**
	ECOSAR (US EPA)	**Daphnid, 48-hr, LC50**	**Free**
	T.E.S.T. (US EPA)	**Daphnia magna LC50 (48 hr)**	**Free**
	VEGA (DEMETRA)	**Daphnia Magna LC50 (48 h)**	**Free**
	ADMET Predictor (Simulations Plus)	**Toxicity module**	**Commercial**
	Discovery Studio (Accelrys)	**Daphnia EC50**	**Commercial**
Long-term toxicity to aquatic invertebrates (daphnia)	**ECOSAR (US EPA)**	**Daphnid, ChV11**	**Free**
Toxicity to aquatic plants (algae)	**Danish QSAR Database (DTU)**	**Pseudokirchneriella s. 72h EC50 from DTU**	**Free**
	ECOSAR (US EPA)	**Green Algae, 96-hr, EC50**	**Free**

Table 3.11. A non-exhaustive list of (Q)SAR programs available for ecotoxicological endpoints

Therefore, the two requirements that should in all cases be asked in order to ensure reliability, are that the (Q)SAR model is scientifically **validated** and that the chemical under evaluation is in the **applicability domain of the (Q)SAR model**[30]. The concept of AD was introduced to assess the probability of a chemical being covered by the (Q)SAR training set. Predictions outside the AD are normally not reliable and their use is hard to justify. Therefore, the applicability domain and the limitations of the model have to be described to allow the assessment of the AD for the specific prediction.

With regards to the stakeholder´s comment on the error allowed in the prediction and the coefficient, it should be noted that, one of the principles for validating the (Q)SAR models is the **appropriate measures of goodness-of-fit, robustness and predictivity**. This principle expresses the need for **statistical validation of the model**. For instance, for regression models, the statistics of the regression model could be reported through the **correlation coefficient (R2)**, cross-validated (e.g. from leave-one-out procedure) correlation coefficient (Q2) and the **standard error of the model (s).** It can be noted that an **R2 below 0.7**, a Q2 below 0.5 or an **s above 0.3 should warn the (Q)SAR user of a potential low performance of the (Q)SAR model**.

[30] Note that a valid (Q)SAR model does not necessarily produce a valid prediction. It is necessary to assess whether the substance falls within the applicability domain of the (Q)SAR model. Section 3 of ECHA Guidance – *Practical guide how to use and report (Q)SARs* in detailed the five principles that a (Q)SAR model should be followed for its validating.

In general, there is no formal adoption process existing or foreseen for (Q)SAR models, nevertheless for the EU Ecolabel, the **validity and applicability**[31] of (Q)SAR models shall be provided by the applicant with the prediction generated for the target chemical.

In consequence, the text in the assessment and verification has been updated so that the prediction from a model without information on the validity and applicability domain shall not be accepted.

With regards to the proposal to add the fish embryo toxicity (FET) test according to OECD 236 as a non-animal alternative to the acute fish toxicity test, it should be noted that according to the OECD Environment, Health and Safety Publications, Series on Testing and Assessment No.99 "Comparison between OECD Test Guidelines and ISO standards in the areas of ecotoxicology and health effects" the Fish, Acute Toxicity Test **OECD TG203**, is equivalent to the **ISO 7346**. Moreover, according to ECHA, the **OECD 236: Fish Embryo Acute Toxicity (FET) test, was approved in July 2013**[32]. The short-term toxicity test on fish is a standard information requirement under Annex VIII, 9.1.3. In ECHA´s opinion, the results of the TG 236 would usually not be sufficient alone to meet the information requirement of Annex VIII, 9.1.3. In the light of the analysis made by ECHA, there are certain limitations in the use of this test guideline and the registrant, who wants to adapt/waive the standard test, needs to take these limitations into account.

Based on the current knowledge, ECHA considers that **OECD TG 236 might be used within a weight of evidence approach** together with other independent, adequate, relevant and reliable sources of information leading to the conclusion that the substance has or does not have a particular dangerous property (**for further information see Annex XI, 1.2 to the REACH Regulation**). Moreover, the EURL ECVAM position on the Fish Embryo Acute Toxicity Test Method is that the FET can provide information on acute fish toxicity comparable to that derived from standard tests (e.g. OECD TG203)[33]. The potential limitations of the test are explicitly mentioned in the OECD test guideline. The test method **OECD TG 236** is equivalent to **Part C.49** of the annex to Regulation (EC) No 440/2008.

It should be noted that this test is currently not included in the Blue Angel RAL-UZ 178 approach, but it will be considered for its revision. Based on this and in order to not perform animal tests with vertebrates (fish) for the purpose of EU Ecolabelling, FET test has been suggested to be accepted **when fish acute aquatic toxicity data need to be generated** for **acute aquatic toxicity data.** Consequently, the text in the assessment and verification has been updated.

Another proposal was related to the deletion of the recommended guidelines for the preparation of a water-accommodated fraction, since they refer to the addition of poorly soluble substances to biodegradation tests, but not to the preparation of WAFs for ecotoxicity testing, the relevant standards and guidelines for the WAF preparation. ISO/DIS 10634 is a guide for the preparation and treatment of poorly water-soluble organic compounds for the subsequent evaluation of their biodegradability in an aqueous medium. OECD 301 (1992) is a test Guideline that describes six

[31] More information available online at ECHA Guidance – *Practical guide how to use and report (Q)SARs- section 3*: https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf/407dff11-aa4a-4eef-a1ce-9300f8460099

[32] More information available online at: https://echa.europa.eu/documents/10162/21650280/oecd_test_guidelines_aquatic_en.pdf/2548af92-ffe1-4e38-a42a-463103b1586f

[33] More information available online at: https://ec.europa.eu/jrc/sites/jrcsh/files/eur_26710_eurl_ecvam_zfet_recommendation__online.pdf

methods that permit the screening of chemicals for ready biodegradability in an aerobic aqueous medium. The annex III refers to the evaluation of the biodegradability of poorly soluble compounds. The OECD 310 (Ready Biodegradability - CO_2 in sealed vessels (Headspace Test)) is a screening method for the evaluation of ready biodegradability of chemicals. Therefore, effectively these references refer to the addition of poorly soluble substances to biodegradation tests but not to the preparation of WAFs for ecotoxicity testing. These references have been deleted and replaced by:

- ECETOC Technical Report No 26 (1996) Aquatic Toxicity Testing of Sparingly Soluble, Volatile and Unstable substances which refer to the preparation of WAFs for ecotoxicity testing in Appendix C.
- OECD 2002. Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures. OECD Series on Testing and Assessment, No. 23.
- ISO 5667-16 Water quality - Sampling - Part 16: Guidance on biotesting of samples.
- ASTM D6081-98 (Standard practice for Aquatic Toxicity Testing for Lubricants: Sample Preparation and Results Interpretation or equivalent methods)

Finally, a proposal for the Alignment between *OECD Guidelines for the testing of chemicals* (OECD Test Guidelines) and corresponding standards of the *International Organisation for* Standardization (ISO) in the area of environmental effects (toxicity to aquatic organisms) was made. It should be noted that the list of ISO/ EU/OECD test guidelines has been updated in the revised criterion according to the comments and validated test methods for aquatic toxicity published by EURL ECVAM[34].

Summarising, based on the comments received during and after the 2nd AHWG meeting and further research carried out, main changes and conclusions for the third proposal related to the assessment and verification of criterion 2 are summarized below:

- The *OECD Guidelines for the testing of chemicals* (**OECD Test Guidelines**) and their corresponding standards of the *International Organisation for Standardization* (**ISO**) has been updated according to the validated test methods for aquatic toxicity published by EURL ECVAM.
- **Fish embryo toxicity (FET)** (non-animal alternative) test according to OECD 236 has been included for determining acute aquatic toxicity the when new **fish acute aquatic toxicity data need to be generated to the applied lubricant**.
- Guidelines for the preparation of a water-accommodated fraction have been updated accordingly for ecotoxicity testing.
- In relation to QSARs the assessment and verification has been amended to include that predictions from (Q)SAR models without information on the validity and applicability domain shall not be accepted.

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within the assessment and verification section within criterion 2 as a result of the final consultation:

- An expert proposed to to add also algae (same methods but endpoint NOEC for chronic toxicity): ISO 10253 or ISO 8692 or OECD Test Guideline 201 or Part

[34] More information available on line at: https://eurl-ecvam.jrc.ec.europa.eu/validation-regulatory-acceptance/environmental-toxicity-fate/Env-Aquatic-Toxicity

C.3 of the Annex to Council Regulation (EC) No 440/2008 for algae. This proposal has been accepted.

Relevant information to be included in User Manual for Guidance related to criterion 2:

- Guidance on how to convert different units for acute toxicity. Concentration can be expressed in mass per volume units or moles per volume, nevertheless the molecular weight will allow converting from moles to mass.
- Additional practical information with regards OECD tests. For example:
  - For algae, test duration according to ISO/DIS 10253 or ISO 8692 or OECD Test Guideline 201 or Part C.3 of the Annex to Regulation (EC) No 440/2008 is normally 72 hours. However, shorter or longer test durations may be used provided that all validity criteria can be met. The test period may be shortened to at least 48 hours to maintain unlimited, exponential growth during the test as long as the minimum multiplication factor of 16 is reached. The aquatic plant growth inhibition tests are normally considered as chronic tests but the EC_{50} is treated as acute value for classification purposes.
  - OECD 236: Fish Embryo Acute Toxicity (FET), July 2013. This text is designed to determine acute toxicity of chemicals on embryonic stages of fish. OECD TG 236 and part C.49 of the Annex to Regulation (EC) No 440/2008 might be used within a weight of evidence approach together with other independent, adequate, relevant and reliable sources of information leading to the conclusion that the substance has or does not have a particular dangerous property (for further information see Annex XI, 1.2 to the REACH Regulation).
- Practical guide How to use and report (Q)SARs is available on-line at webpage: https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf/407dff11-aa4a-4eef-a1ce-9300f8460099 and Chapter R.6: QSARs and grouping of chemicals, available on-line at webpage: https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

3.3 CRITERION 3: Biodegradability and bioaccumulative potential

Final proposal for criterion 3: Biodegradability and bioaccumulative potential

Requirements for the biodegradability of organic compounds and bioaccumulative potential shall be fulfilled by each intentionally added or formed substance at or above the concentration of 0,10 % weight by weight in the final product.

The lubricant shall not contain substances that are both non-biodegradable and (potentially) bioaccumulative. However, the lubricant may contain one or more substances with a certain degree of degradability and potential or actual bioaccumulation up to a cumulative mass concentration as indicated in Table 4.

Table 4. Cumulative mass percentage (%w/w) limits for substances present in the product with respect to their biodegradability and bio-accumulation potential

	ALL	PLL	TLL	Greases (ALL,PLL,TLL)

Readily aerobically biodegradable	**> 90**	**> 75**	**> 95**	**> 80**
Inherently aerobically biodegradable	**≤ 10**	**≤ 25**	**≤ 5**	**≤ 20**
Non-biodegradable and non-bioaccumulative	**≤ 5**	**≤ 20**	**≤ 5**	**≤ 15**
Non-biodegradable and bioaccumulative	**≤ 0,1**	**≤ 0,1**	**≤ 0,1**	**≤ 0,1**

Assessment and verification: For each applicable substance where the assessment is carried out by the applicant, test reports or literature data including the references on the biodegradability and when required on the (potential) bioaccumulation shall be provided.
For each applicable substance where the assessment is based on a valid letter of compliance (LoC), only a copy of the letter shall be provided.
For each applicable substance selected from the Lubricant Substance Classification list (LuSC-list) the assessment can be based on the information reported in said list and no documents need to be submitted.

Biodegradation

'**Inherently biodegradable**' means a substance, which achieves the following level of degradation:

> 70 % after 28 days for inherent biodegradation test, or

> 20 % but < 60 % after 28 days in tests based on oxygen depletion or carbon dioxide generation.

Inherent biodegradability shall be measured in accordance with the following tests:

- Regulation (EC) No 440/2008([24]) (Part C.9 of the Annex), OECD 302 or equivalent methods.
- tests based on oxygen depletion or carbon dioxide generation: Regulation (EC) No 440/2008([24]) (Part C.4 of the Annex), OECD 306, OECD 310, or equivalent methods.

'**Readily biodegradable**' means an arbitrary classification of chemicals which have passed certain specified screening tests for ultimate biodegradability; these tests are so stringent that it is assumed that such compounds will rapidly and completely biodegrade in aquatic environments under aerobic conditions. Substances are considered rapidly degradable in the environment if one of the following criteria holds true:

1. if, in 28-day ready biodegradation studies, at least the following levels of degradation are achieved:
   - tests based on dissolved organic carbon: 70 %;
   - tests based on oxygen depletion or carbon dioxide generation: 60 % of theoretical maximum.

These levels of biodegradation must be achieved within 10 days of the start of degradation which point is taken as the time when 10 % of the substance has been degraded, unless the substance is identified as an UVCB or as a complex, multi-constituent substance with structurally similar components. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days; or

2. if, in those cases, where only BOD and COD data are available, when the ratio of BOD5/COD is ≥ 0,5; or

3. if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period.

Ready biodegradability shall be measured in accordance with the following tests:

- Regulation (EC) No 440/2008([24]) (Part C.4, C.5 in conjunction with C.6 and C.42 of the

Annex), OECD 301, OECD 306, OECD 310, or equivalent methods.

Note: Within the frame of this criterion, the 10 day window principle will not necessarily apply. If the substance reaches the biodegradation pass level within 28 days but not within the 10 day time-window a slower degradation rate is assumed.

'**Non-biodegradable**' means a substance which fails the criteria for ultimate and inherent biodegradability.

The applicant may also use read-across data to estimate the biodegradability of a substance. 'Read-across' for the assessment of the biodegradability of a substance shall be acceptable if the reference substance differs by only one functional group or fragment from the substance applied in the product. If the reference substance is readily or inherently biodegradable and the functional group has a positive effect on the aerobic biodegradation, then the applied substance may also be regarded as readily or inherently biodegradable. Functional groups or fragments with a positive effect on the biodegradation are: aliphatic and aromatic alcohol [-OH], aliphatic and aromatic acid [-C(=O)-OH], aldehyde [-CHO], Ester [-C(=O)-O-C], amide [-C(=O)–N or -C(=S)–N]. Adequate and reliable documentation of the study on the reference substance should be provided. In case of a comparison with a fragment, not included above, adequate and reliable documentation of the studies should be provided on the positive effect of the functional group on the biodegradation of structurally similar substances.

Bioaccumulation

The (potential) bioaccumulation does not need to be established when the substance:

- has a MM > 800 g/mol and has a molecular diameter > 1,5 nm (> 15 Å), or
- has an octanol-water partition coefficient, log K_{ow}, value of <3 or > 7, or
- has a measured BCF of ≤ 100 L/kg, or
- is a polymer and its molecular weight fraction below 1.000 g/mol is less than 1 %.

Since most substances used in lubricants are quite hydrophobic the bioconcentration factor (BCF) value should be based on the lipid weight content and care must be shown to ensure a sufficient exposure time. The BCF shall be assessed according to Part C.13 of the Annex to Regulation (EC) No 440/2008([24]) or equivalent test methods.

The log octanol/water partition coefficient (log K_{ow}) shall be assessed according to Part A.8 of the Annex to Regulation (EC) No 440/2008([24]) or OECD 123 or equivalent test methods. In case of an organic substance other than a surfactant where no experimental value is available, a calculation method can be used. The following calculation methods are allowed: CLOGP, LOGKOW, (KOWWIN) and SPARC. Estimated log K_{ow} values obtained by any of these calculation methods < 3 or > 7 indicate that the substance is not expected to bioaccumulate.

Log K_{ow} values are applicable to organic chemicals only. To assess the bioaccumulation potential of non-organic compounds, surfactants, and some organo-metallic compounds, BCF measurements shall be carried out.

Rationale of the proposed criterion text

For the **first revised proposal**, an analysis of other ecolabels and certification systems was performed in order to understand how the issue of biodegradability and bioaccumulation is addressed in respective schemes. In general, values for other schemes (e.g. Blue Angel and Swedish Standard) are more restrictive than EU Ecolabel.

In addition, information about the threshold values of currently awarded lubricants was collected in order to evaluate the level of ambition of the current thresholds.

It was proposed to change the nomenclature of *Ultimately* for *Readily* according to the last version of CLP. Some concern was expressed by industry whether the term "readily biodegradable" implies an obligatory consideration of the 10-day window in the pass level. However, the 10-day window does not apply if the test substance represents a mixture of homologous compounds e.g. technical surfactants.

In relation to **biodegradability**, it was suggested in the first proposal to have more stringent values for readily aerobically biodegradation in the existing categories 1 and 2. The inherent aerobically biodegradability was proposed to be modified for the lubricant products greases and 2-stroke oils; based on the analysis of the current threshold values of the EU Ecolabel products certified.

With regard to **bioaccumulation** values no changes have been proposed during the revision.

In the **second proposal**, it was the reference to ready degradability was decided to be maintained, considering that it includes an exemption of the 10-day window in the pass level for substances identified as UVCB (*Unknown or Variable composition, complex reaction products or biological materials).* In addition, the threshold values were modified to adapt the new thresholds with the revised scope proposal of categorisation. The unification of the previous categories 1 and 5 under ALL, and categories 2 and 4 under PLL has created the need for a new definition of the threshold values. Different considerations were taken into account to define the new thresholds, for instance the risk of spill out and the share of assessed products that comply with the revised thresholds[35].

Other changes included during the second revision cover:

- Adjusting inherent aerobic biodegradation to sum up to 100% when it is combined with readily biodegradability, in order to benefit the totally biodegradable lubricants.
- Reverting the threshold value of readily biodegradation for category 1 (ALL in the second revised proposal) to 90% (which is existing value in force for categories 1 and 5) keeping in mind that TLL should have a higher threshold value (95%) since the probability to release in the environmental is higher.
- Adjusting threshold values for readily biodegradability of PLL (previous categories 2 and 4) considering some comments received about difficulties to comply with the 1st proposal limits for Category 2. The threshold value of readily biodegradability has been reverted to existing value in force (75%).

- **Outcomes from and after the 2nd AHWG meeting**

Few comments about the proposed threshold values for biodegradability were received. It was mentioned that the requirements for PLL category are less though than those of the ALL category, when logically it should be the opposite. Moreover, some critical products were identified as not able to comply with the thresholds: total loss greases (referring to the component lithium hydroxide) and stern tube oils.

With regards to biodegradability, minor changes were asked, e.g. to include some definitions (more information in the separated ANEX: Table of comments published along with TR3.0).

[35] Information provided by competent bodies corresponding to the 40% of licences, included in tables 15, 16, 17, 18 and 19 of the TR.1.0.

- **Further research and main changes in third proposal**

Regarding the threshold values, data provided by competent bodies and stakeholders have been revised, with special attention to greases category. Data for 25 greases certified (or aiming to apply for the EU Ecolabel) was received during the process revision. 20% of them have a threshold value for readily aerobically biodegradability higher than 95%; and 44% of the certified products are >90% readily biodegradable.

From the available information, only 5 out of 24 greases would comply with the limits set for TLL greases. No extra data about distribution of greases depending on the environmental release has been received.

Further, greases applied in open areas are exposed to environmental influences as water, rain and extreme temperatures. The requirements to formulate greases capable to withstand those conditions are stricter. The grease needs a thickener to reach the desired viscosity; as Lithium hydroxy-stearate (Li-HSA). This substance is listed in the LuSC List as non-biodegradable, and the viscosity will need to be achieved with calcium soap instead. The grease for marine applications need performance improving additives, EP as well as AW additives will be essential. A typical minimum amount will be 4% for these non-biodegradable, non-toxic additives. As the calcium and lithium salts are water-soluble, a polymer needs to be included for marine applications, in order to make the grease consistency last longer; up to 5% of polymer can be used; these polymers are usually poorly biodegradable, ranging from inherently-biodegradable to non-biodegradable. Another frequent protective is a metal deactivator, generally at 1%, which are also non-biodegradable non-toxic. As the application points are exposed to salt-water, a booster for corrosion protection is needed, 1-2% of non-biodegradable non-toxic additive. Occasionally CaCO3 may also be needed, which is not counted for biodegradation, as it is inorganic material.

The above considerations lead to the decision to relax the initial proposal for the biodegradability criterion for TLL greases.

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this criterion as a result of the final consultation:

- 11 out of 24 greases currently in EU Ecolabel would comply with the biodegradation criteria included in TR3.0 for TLL greases. No extra data about distribution of greases depending on the environmental release has been received. In the light of the comments received and considering that it is reasonable to conclude that a high percentage of the EU Ecolabel certified greases are TLL applications which are going to be used in sensitive areas, it is therefore suggested to set separated specific values for greases for this revision.

Rationale of proposed assessment and verification

OECD 301B (CO_2 Evolution) and ISO 14593 (Water quality - Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium - Method by analysis of inorganic carbon in sealed vessels) are the most commonly requested methods in the U.S. and Europe for

testing the biodegradation of lubricants[36]. The OECD 301 test is the most extensively used for other ecolabels to evaluate the biodegradability of substances: Korean Ecolabel, Japan Ecolabel, Nordic Swan and Blue Angel.

Other tests used to define the biodegradability are: ISO 14593, 9439 and 9408 (or equivalent) for Nordic Swan, ISO 10708, 9439 and 9408 for Swedish Standard. Blue Angel also relates to other OECD tests: OECD 306, 310 and 302C to verify the ultimate biodegradability and inherent biodegradability.

In the Regulation (EC) No 440/2008[37], OECD 107 test and the method OECD 305 are referred to for testing the bioaccumulation potential. Also Blue Angel accepts this test.

The first proposal consisted of asking for test reports or literature data about the biodegradability and bioaccumulation potential (if required). This was considered however not clear enough. After the first consultation, the majority of the wording of current text in force was reintroduced. An extension of the description of the assessment and verification was made, in order to clarify some concepts and methods relevant for the criterion.

In the first proposal the requirements to establish bioaccumulation of a substance were suggested to be modified according to the last version of CLP Regulation. In the 1st AHWG the following values were presented: log K_{ow} value of < 4 or >7 and BCF of ≤ 500 L/kg. However, during the consultation process it was discussed and agreed to keep the current formulation of the criterion with the strict values of the BCF and the lower limit of log K_{ow} and not to align them with the less strict threshold given in CLP Regulation.

With regards to the BCF and log K_{ow}, in the second proposal the current values in force were suggested to be kept except of the upper limit of log K_{ow}. It seems that there is no consistent justification of the current value of 7, because there is no evidence standing up that a substance is not bioaccumulative when log K_{ow} > 7. Following this approach, in the second proposal a cut-off for the log K_{ow} of 10 was suggested. This value was defined according the rationale of Dimitrov et al. (2002)[3839], who supported that within a Weight-of-Evidence a substance may not be bioaccumulative for log K_{ow} higher than 10. The bioaccumulation of a substance is difficult to measure for log K_{ow} values higher than 10, the reliability of a modelled K_{ow} values > 10 is not known.

- **Outcomes from and after the 2nd AHWG meeting**

Few comments were received along the 2nd AHWG meeting and posterior consultation in relation to test methods. OECD 306 test method was proposed to be included as a method for determining also the readily biodegradability of substances. The OECD 306 and OECD 301 tests should be considered as acceptable and equivalent for both requirements: readily and inherently biodegradability.

[36] http://www.situbiosciences.com/lubricant-biodegradation-and-toxicity-testing/

[37] COUNCIL REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

[38] Guidance on Information Requirements and Chemical Safety Assessment Chapter R.11: PBT/vPvB Assessment. More information available online at: https://www.echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

[39] Dimitrov SD, Dimitrova NC, Walker JD, Veith GD and Mekenyan OG (2002) Predicting bioconcentration factors of highly hydrophobic chemicals: effects of molecular size. Pure and Applied Chemistry 74:1823-30.

The 10-day window test included in the definition of readily biodegradability was a controversial issue. It was commented that the inclusion of this concept in the definition is too restrictive.

All stakeholders disagreed with the proposal to change log K_{ow}; however different proposals were presented:

- Maintain the existing values: log k_{ow} < 3 or >7.
- Set new upper limit: log k_{ow} < 3 or >8.

Analysis of stakeholders' responses showed that the preferred option was to set the existing value of log K_{ow} <3 or >7. Different justifications were provided during the meeting and also in the comments; for instance that the proposed limit is too ambitious because current available OECD methods are not able to measure log K_{ow} beyond 10. Relevant information was provided to justify the reduction of the upper limit.

Regarding the bioaccumulation, different stakeholders asked about a clarification for the cases when the bioaccumulation potential is not needed because a substance is biodegradable to be included. One stakeholder commented that BCF value is less restrictive; BCF value of < 500 (or preferably < 1000) should be considered (more information in the separated ANEX: Table of comments published along with TR3.0).

- **Further research and main changes in the third proposal**

Some changes have been introduced in the assessment and verification text, in order to respond to the feedback from stakeholders. Among them the modification of the test methods: C.42 in readily biodegradability, and OECD 302 for inherently biodegradability.

The test method C.42 was amended in March 2016[40]. It is equivalent to OECD 306. In reference to OECD 306, it is not specified in the criterion text because it is understood to be included as one of the equivalent methods.

In the first revised version only the OECD 302C test was included to calculate the inherently biodegradability. After a stakeholder proposal, also the OECD 302B has been considered as method to measure this biodegradability. A summary of this methods are included in the following table[41]:

Guideline	Test	Water solubility/ volatility	Measured parameter
OECD 302B	Zahn-Wellens- Test	Water soluble Non- volatile, non-foaming	DOC (Dissolved Organic Carbon)
OECD 302C	Modified MITI Test (II)	Non water soluble/ Soluble Non- volatile, volatile	CO_2 pressure decrease (BSB-Sensomat flasks) and DOC (Dissolved Organic Carbon) or additional analytical method

[40] COMMISSION REGULATION (EU) 2016/266 of 7 December 2015 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0266&from=EN

[41] https://www.ibacon.com/your-study-type/chemistry/oecd-302-inherent-biodegradability-tests

The definition of readily biodegradable was maintained. However also is included that for substances identified as UVCB (Unknown or Variable composition, complex reaction products or biological materials) or as a complex, multi- constituent substance with structurally similar constituents exemption from the 10-day window can be applied. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days.

After the comments received from stakeholders on difficulty to comply with the proposed upper limit of log K_{ow} it was understood that none of the existing OECD methods include the possibility of measuring log K_{ow} >10, being the upper measurable precision limit 8,2.

Below the main used methods to determine log K_{ow} of a substance are listed:

Test method	Limit values determined
OECD 107	Log K_{ow} between 2 and 4
OECD 117	Log K_{ow} between 0 and 6
OECD 123	Log K_{ow} between 0 and 8,2

The estimation of the bioconcentration for substances with log k_{ow} >8 is surrounded with a number of uncertainties leading to estimation methods. At log K_{ow} values between 4 and 5, the bioconcentration factor increases linearly with Log K_{ow}. However, for higher values of log K_{ow} (higher than 6), the linear relationship decreases. In the following graphic the relation of the bioconcentration factor and the log K_{ow} could be seen[42]:

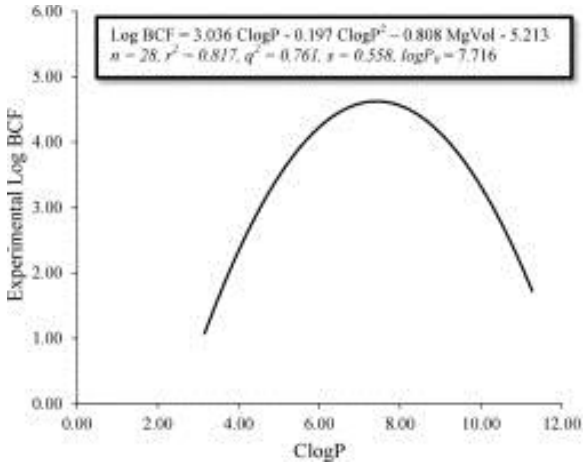


Figure 1. Correlation of the experimental log BCF values with experimental log K_{ow}.[42]

Despite the relationship between both parameters are not linear for higher values of log k_{ow} than 6, the bioconcentration potential of substances with log of 8 are still significant and in the environmental hazard limit.

Most models predicting log K_{ow} are not validated above a log K_{ow} value of 8, due to current techniques for the determination of log K_{ow} are not able to determine higher values.

Moreover, other evidences have been analysed:

- According the the Blue Angel criteria the accumulation is assumed only when the log K_{ow} value is <3. However, an exemption is included and substances with log K_{ow} values > 6.0 may be permitted if technically justified.

[42] Predicting the bioconcentration factor of highly hydrophobic organic chemicals. https://ac.els-cdn.com/S0278691514001641/1-s2.0-S0278691514001641-main.pdf?_tid=7578724e-de70-11e7-a225-00000aacb35d&acdnat=1512996204_ebc8d62cfd3d3303b8df8c7c1f96a887

- Others product groups of EU Ecolabel (detergents and paints) define a substance as non-bioaccumulative if the BCF is < 100 or log K_{ow} < 3; not including an upper value for log K_{ow}.

Finally, available data from SDS has been considered to understand the impact of the modification in the upper threshold value of log K_{ow} on the LuSC-list. If the upper limit is modified to 8, only 7% of the substances listed will be affected. In fact, half of the substances included in the LuSC-List have a log K_{ow} <3 or >8. However a limited number of SDSs from LuSC list has been provided to us for the assessment.

Against this background, it was suggested in the **third proposal** to set a log K_{ow} value of 8.

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within the assessment and verification section for this criterion as a result of the final consultation:

- Considering the uncertainty related to the impact on current licenses it is suggested to keep the possibility to waive the 10 day window for this revision. However, for future revisions it is proposed to explore in detail data on current licenses with this regards at an early stage of the revision, in order to know with certainty the impact of introducing the 10 day window in future revision. For this revision, it is therefore suggested to include a note within the criterion text, in line with current text in force and Blue Angel.

- Considering the continuous opposition during the process from industry side and the uncertainty related to the impact on current licenses it is suggested to keep existing log log K_{ow} value for this revision.

- Any additional, more specific information regarding testing is suggested to be included in the User Manual

3.4 Criterion on raw materials

Criterion on raw materials is proposed to be finally deleted.

With regard to the renewable raw materials, the existing criteria in force (Criterion 5: Renewable raw material) only requires a minimum percentage of renewable content in order to enforce renewable ingredients.

Nevertheless, as mentioned in the chapter 1.2.2 other options are currently available on the market such as re-refined and synthetic base oils that potentially could have lower environmental impacts than mineral oils; although it would depend not only on the type but also on the application of the lubricant. With modern re-refining technologies, CO_2 emissions from the re-refined oils can be reduced by more than 50% compared to the conventional production of base oil[43]. However the inclusion of this base oil will not satisfy the requirements on toxicity and biodegradability. A draft of a broader criterion considering other alternatives to pure mineral lubricants (i.e. synthetic or re-refined origin) was proposed for discussion for the 1st AHWG meeting.

In addition, for the **first proposal**, a revision of the thresholds was carried out based on the analysis of values of the current EU Ecolabel products and other Ecolabel schemes. More restrictive thresholds were proposed in the first proposal, when compared with the currently valid ones. The results of the consultation of competent bodies and industry stakeholders with regard to existing renewability thresholds are available in the 1st draft of the technical report (TR1.0).

During the 1st AHWG meeting, the criterion of the current decision was seen as controversial. Other outcomes of the meeting were:

- Stakeholders asked for more evidence and information about the impacts of different lubricants base fluids.
- The inclusion of re-refined oils was not welcome.
- Greases would not be able to comply with the new threshold values.
- The need to clarify synthetic lubricants.

Against this background, re-refined oils were excluded in the **second proposal**. For loss lubricants applications for which toxicity and biodegradability are core aspects, the inclusion of derogations in aquatic toxicity and biodegradability needed for re-refined oils is not considered appropriate.

For the second proposal, the criterion was further defined. In addition to bio-based lubricants, there are several alternatives to conventional mineral lubricants that present good biodegradability potential, low toxicity and are not bioaccumulative, and therefore could be suitable alternatives for lubricants included in the scope of this EU Ecolabel. Synthetic base oils from non-renewable resources could comply with criteria 1, 2 and 3, because they have good biodegradability potential and low toxicity (some of them are included in the Environmental Acceptable Lubricants).

In the second proposal for this criterion, besides the renewable carbon content, PAGs, PAOs and non-renewable ester base oils were suggested to be considered in line with the Environmental Acceptable Lubricants (EAL).

[43] GEIR Fishing Vessel registered in Norway: position (GEIR: Groupement Européen de l'Industrie de la Régénération)

- **Outcomes from and after the 2nd AHWG meeting**

It seems that there is no a clear overview of the criterion proposal. Moreover, a general comment was about the lack of equality of treatment between different base fluids. Renewable lubricants have to comply with higher severity requirements on raw material.

The inclusion of non-renewable sources in the scope is not welcomed by everyone. Different viewpoints were presented during the consultation:

- If the non-renewable sources are included in the scope, an EU Ecolabel lubricant will not be able to be classified as "*biolubricant*". Some stakeholders asked for a minimum of 25% of renewable sources, to be in line with the biolubricants standard CEN - EN 16807.
- The inclusion of a renewable fraction defines automatically the use of non-renewable base fluids to comply with the criterion.
- The non-renewable sources included in the criterion will not comply with the biodegradability criterion.
- Mineral oils have an intrinsic environmental impact, linked with the toxicity of the product.

On the other hand, a group of stakeholders agreed with the inclusion of non-renewable sources. However, different approaches were presented related with this topic: some stakeholders only commented on the inclusion of a specific synthetic lubricant (all synthetic esters, gas-to-liquid), and other stakeholders requested that the scope be open to all those lubricants that are compliant with other requirements.

Some comments favoured deleting Criterion 4 (and Criterion 5): *if the proposed policy to allow non-renewable synthetic esters, PAOs, and PAGs at any percentage, including 100% is adopted, then Criterion 4 is not needed*. Moreover, other sustainable labels or legislations do not include a minimum content of renewable materials.

- **Further research and main changes in the third proposal**

The EU Ecolabel is a label that allows consumers to identify environmentally friendly high quality products and services. It is not a label specific for biobased products. Other ecolabels, such as Blue Angel, US-VGP and Swedish Standard, follow this approach and do not require a minimum percentage of renewable raw materials.

In addition, due to the varying scope and system boundaries of the available LCA studies and the particular issues which are characteristic of this industry, it has not been possible to perform a robust comparison between different base oils in the market. Moreover, current life cycle impact method does not cover properly toxicity and biodegradability, important issues to consider in case of spillage of the lubricant in the environment. For this reason, it is suggested to set the focus of this criteria set on biodegradability and toxicity rather than in the base fluid nature. It is therefore proposed to follow a technology neutral approach. The deletion of criterion 4 on renewability opens the scope to all the lubricants that are able to comply with criteria 1, 2 and 3, and the renewability is not limiting the certification of a lubricant. Moreover, the scope is open to accommodate the development of new technologies in the lubricant industry.

- **Outcomes from last written consultation and final changes**

No changes are proposed in the followed approach as a result of the last written consultation. Detailed comments/responses in the ANEX: Table of comments.

3.5 CRITERION 4: Origin and traceability and advertising of renewable raw materials

Final proposal for criterion 4: Renewable ingredients requirements
a) In the specific case of renewable ingredients from palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, 100% w/w of the renewable ingredients used shall meet the requirements for sustainable production of a certification scheme that is a multi- stakeholder organisation with a broad membership, including NGOs, industry and government and that addresses environmental impacts on soil, biodiversity, organic carbon stocks and conservation of natural resources. b) If the term "bio-based" or "bio-lubricant" is used, the minimum bio-based carbon content in the final product shall be 25% in accordance with EN 16807. ***Assessment and verification*** To demonstrate compliance with criteria 4 (a) evidence through third-party chain of custody certificates that the input materials used in the manufacturing originate from sustainably managed plantations shall be provided. Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models: identity preserved, segregated, mass balance shall be accepted. For palm oil and palm kernel oil derivatives, the amounts of RSPO credits purchased and claimed in the RSPO PalmTrace system model during the most recent annual trading period shall be provided to demonstrate compliance to the Book and Claim supply chain model. To demonstrate compliance with criteria 4 (b) the applicant shall enclose the final product test report in accordance with EN 16807, ASTM D 6866, DIN CEN/TS 16137 (SPEC 91236), EN 16640 or EN 16785-1.

Rationale of the proposed criterion text

Renewable raw materials used in the production of lubricants are basically vegetable oils, animal oils and greases. Vegetable oils used in lubricants are mainly rapeseed, sunflower, palm and coconut. Derivatives of these oils are also used for producing lubricants. In Europe, rapeseed and sunflower oils are the major vegetable oils used for industrial purposes, including lubricant production[44]. Palm oil is less favourable because it tends to solidify at low temperatures. However palm oil does possess good properties for lubricants, such as good oxidative stability, good adherence to metal and it is cheaper compared to other vegetable based oils. For these reason, it has also penetrated the lubricant industry.

Vegetable oils have environmental advantages over mineral or non-bio-based synthetic oils in terms of biodegradability and toxicity. However, these advantages can be counterbalanced by the environmental impacts associated with non-sustainable agricultural practices. Palm and soybean oils are seen as the more controversial, because of the issue of deforestation and land use change (direct and indirect) involving loss of natural habitats, associated with their plantations in Southeast Asia and Amazon rainforest.

To address the socio-economic issues and minimise the environmental impacts related to the cultivation of these oil producing plants, some voluntary sustainability certification schemes have been developed. These include: ISCC (International Sustainability and Carbon

[44] Cuevas, P. (2010). Comparative life cycle assessment of biolubricants and mineral based lubricants (Doctoral dissertation, University of Pittsburgh).

Certification), RSPO (Round Table on Sustainable Palm Oil), RSB (Roundtable on Sustainable Biomaterials) bioproduct standard, as well as several others. Detailed information on a few of these schemes is provided in the Appendix 2 in Technical Report 2.0. Table 3.12, shows a summary of a review through the schemes documentation and related literature to identify reference schemes that fulfilled most of the requirements detailed in the mentioned directive and regulation and could be potentially used for this criterion. It is pertinent to note that not all the voluntary sustainability schemes available have been reviewed. For simplicity and considering the broader implications of the EU Ecolabel criteria, only schemes with a global coverage have been considered.

Several policies and standards regarding bio-based products exist at the European level[45] in the framework of the European policy aimed at promoting sustainable bio-based products which can make the economy more sustainable and lower its dependence on fossil fuels. The bio-based product market was identified as a lead market by the European Commission's Lead Market Initiative. The Lead Market Initiative aims to support the up-take of a series of specific sectors by using policy instruments such as regulation, public procurements, standardization and other supporting activities, in order to lower barriers to bring these new products into the market.

Within this framework, the European Committee for Standardisation (CEN) is currently developing standards under the following Mandates in the area of bio-based products, including:

- M/430 on bio-polymers and bio-lubricants
- M/491 on bio-solvents and bio-surfactants (already completed)
- M/492 for the development of horizontal standards for bio-based products
- M/547 on algae and algae-based products or intermediates

The **CEN Technical Committee 'Bio-based products' (CEN/TC 411)** develops standards that cover horizontal aspects of bio-based products. The standards that are being developed in the framework of EC Mandate 492 are mainly focused on bio-based products other than food and feed or biomass for energy applications. European Standards and other standardization deliverables have been or are being developed in relation to the following horizontal aspects of bio-based products:

- Common terminology (EN 16575)
- Methods for determining bio-based content (CEN/TR 16721, CEN/TS 16640, EN 16785)
- Sustainability aspects (EN 16751)
- Life Cycle Assessment (EN 16760)
- Declaration tools

- **<u>EN 16751:2016. Bio-based products - Sustainability criteria</u>**

This standard sets horizontal sustainability criteria applicable to the bio-based part of all bio-based products; excluding food, feed and energy, covering the three pillars of sustainability; environmental, social and economic aspects. If the product is partly bio-based, this European standard can only be used for the bio-based part since it does not address non-bio-based (fossil, mineral) parts of a product. This European standard can be used for two applications; either to provide sustainability information about the biomass production only or to provide sustainability information in the supply chain for the bio-based part of the bio-based product.

[45] http://ec.europa.eu/growth/sectors/biotechnology/bio-based-products_es

This standard sets a framework to provide information on the management of sustainability aspects. It cannot be used to make claims that operations or products are sustainable since it does not establish thresholds or limits. However, it can be used for business-to-business (B2B) communication or for developing product specific standards and certification schemes.

The European Union Renewable Energy Directive (RED) 2009/28/EC

The **RED**[46] outlines sustainability criteria for bio-fuels produced or consumed in the EU to ensure that they are produced in a sustainable and environmentally friendly manner. Companies can show they comply with the sustainability criteria through national systems or so-called voluntary schemes recognised by the European Commission. The EU has defined a set of sustainability criteria to ensure that the use of bio-fuels (in transport) and bio-liquids (for electricity and heating) is carried out in a way that guarantees real carbon savings and protects biodiversity.

In the European Union, under the RED, only biofuels and bioliquids produced from verifiably certified sustainable biomass can receive state support and may be counted towards national renewable energy targets. For this purpose a set of EU's sustainability criteria was defined in ***Article 17: Sustainability criteria for biofuels and bioliquids.*** The main points referred to are:

- Greenhouse gas emissions saving from the use of biofuels and bioliquids.
- Biofuels and bioliquids shall not be made from raw material obtained from land with high biodiversity value.
- Biofuels and bioliquids shall not be made from raw material obtained from land with high carbon stock, namely wetlands, continuously forested areas, land with mature trees.
- Agricultural raw materials cultivated accordance with the requirements and standards establishing common rules for direct support schemes for farmers.
- Issues related to the impact on social sustainability in the Community and in third countries of increased demand for biofuel; the availability of foodstuffs at affordable prices; respect of land-use rights and Conventions of the International Labour Organisation.

Compliance with the criteria can be demonstrated through participation in one of recognised voluntary schemes[47], some of which are:

- ISCC (International Sustainability and Carbon Certification)
- Bonsucro EU
- RTRS EU RED (Round Table on Responsible Soy EU RED)
- RSB EU RED (Roundtable of Sustainable Biofuels EU RED)
- 2BSvs (Biomass Biofuels voluntary scheme)
- RBSA (Abengoa RED Bioenergy Sustainability Assurance)
- Greenergy (Greenergy Brazilian Bioethanol verification programme)
- Ensus voluntary scheme under RED for Ensus bioethanol production
- Red Tractor (Red Tractor Farm Assurance Combinable Crops & Sugar Beet Scheme)
- SQC (Scottish Quality Farm Assured Combinable Crops (SQC) scheme)
- Red Cert
- NTA 8080
- RSPO RED (Roundtable on Sustainable Palm Oil RED)

[46] Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC.
[47] For more information see the following webpage: https://ec.europa.eu/energy/node/74

- BioGrace GHG calculation tool
- HVO Renewable Diesel Scheme for Verification of Compliance with the RED sustainability criteria for biofuels
- Gafta Trade Assurance Scheme
- KZR INIG System
- Trade Assurance Scheme for Combinable Crops
- Universal Feed Assurance Scheme
- The Approved Austrian National Scheme - Austrian Agricultural Certification Scheme

Detailed information on a few of these schemes is provided in the Appendix 2 in Technical Report 2.0.

Table 3.12, shows a summary of a review through the schemes documentation and related literature to identify reference schemes that fulfilled most of the requirements detailed in the mentioned directive and regulation and could be potentially used for this criterion. It is pertinent to note that not all the voluntary sustainability schemes available have been reviewed. For simplicity and considering the broader implications of the EU Ecolabel criteria, only schemes with a global coverage have been considered. The schemes examined fulfilled the same similar basic criteria detailed in the EU RED, with some being exceptional due to the additional stringent criteria required via their add-on modules (e.g. ISCC Plus an add-on to ISCC, RSPO Next an add-on to RSPO).

The potential of these schemes (low, medium, high) to be used for verifying that the bio-based materials being used in the manufacture of biolubricants has been defined according to the scope of the certification and the degree of maturity of each scheme, and the market availability of biolubricants containing certified renewable raw materials. Several sources[48,49,50,51] revealed that there are bio-based lubricant producers who utilize a mixture of certified sustainable renewable materials from different schemes in their biolubricant production process.

[48] http://www.agrobiobase.com/en/database/bioproducts/maintenance/berylane-biolife
[49] http://www.chemanager-online.com/en/topics/chemicals-distribution/peter-greven-extends-lubricant-portfolio-rspo-certified-products
[50] http://www.emeryoleo.com/OleoBasics.php
[51] http://www.emeryoleo.com/content/Emery_BL_brochure.pdf

Table 3.12:Summary of the different available schemes for bio-based products

General considerations and criteria scope	ISCC	RSPO	RSB	RTRS
Voluntary	Yes	Yes	Yes	Yes
Global in geographical scope, comprehensive coverage of criteria and not only EU RED, multi-stakeholder scheme	Yes	Yes	Yes	Yes
EU Recognized	Yes (but only for EU RED)	Yes (but only RSPO RED Scheme[52] for EU RED)	Yes (but only for EU RED)	Yes (but only for EU RED)
Applicable renewable feedstock[53]	All types of feedstock	Only Palm Oil, Palm Kernel Oil and their derivatives	All types of feedstock	Only Soy
Market uptake for certification of feedstocks for non-biofuel sector[54]	High	High	High	Medium
Biolubricants in market with certified bio-based content	Yes (Certification schemes applied is a combination of RSPO and the ISCC Plus addon of the ISCC Scheme)	Yes (Certification schemes applied is RSPO Scheme)	Yes	Yes
Certifications available	ISCC Plus / ISCC EU (Biofuel)	RSPO / RSPO NEXT	Production / chain custody standard	Production / chain custody standard
Ecological (EU RED 2009 (Art.17))	Yes	Yes	Yes	Yes
Reduction of environmental impacts EU RED 2009 (Art.17, focus on GHG reduction)	Yes	Yes	Yes	Yes
Energy (EU RED 2009 (Art.17)	Yes	Yes	Yes	Yes
High Carbon stocks & biodiversity (EU RED 2009 (Art.17))	Yes	Yes	Yes	Yes
Land use change (EU RED 2009 (Art.17))	Yes	Yes	Yes	Yes
Traceability (EU RED 2009 (Art.18), EU RED 2016 (Art. 25))	Yes	Yes	Yes	Yes
Accreditation (EU RED 2009 & EU RED 2016)[55]	No	Yes	Yes	No
Social and labour (EU RED 2009 (Art.17))	Yes	Yes	Yes	Yes
Water (EU RED 2009 (Art.17, 18))	Yes	Yes	Yes	Yes

[52] http://ec.europa.eu/energy/en/topics/renewable-energy/biofuels/voluntary-schemes
[53] http://english.rvo.nl/sites/default/files/2013/12/Report%20certification%20schemes%20-%20Partners%20for%20Innovation%20-%20NL%20Agency%20DEF.pdf
[54] https://www.iisd.org/pdf/2014/ssi_2014_chapter_6.pdf
[55] http://ec.europa.eu/energy/sites/ener/files/documents/1_en_annexe_proposition_part1_v9.pdf

Other Ecolabels have explored the possibility of setting criteria regarding the origin of vegetable oils, although concluding that these issues would be further analysed in future revisions (Japanese Ecolabel from 2004, Blue Angel for Biodegradable Lubricants and Hydraulic Fluids (RAL-UZ 178) in the year 2014).

Other product groups from EU Ecolabel (namely Rinse-off cosmetics and Detergents and cleaning product groups) include certain criteria regarding the sustainability of vegetable oils, but limited them to palm oil and palm kernel oil and their derivatives only[56].

In the **first technical report TR1.0** it was proposed to include this new criterion *(Criterion 5: Origin and traceability of vegetable raw materials)* promoting the sustainable production of vegetable based raw materials to ensure that they originate from well managed sources. It was suggested to provide supply-chain-evidence that the vegetable renewable raw materials originate from certified and well managed sources.

Nevertheless, some difficulties to define a proper verification through a third party certification scheme arose from the first proposal. From the 1st AHWG meeting most of comments received argued that the incorporation of this criterion for this revision was not feasible, since only few well-established third-party certification schemes for renewable oils were available and not all of them are recognised across EU. However some stakeholders suggested conducting additional research on all the available initiatives. Some standards, directives, legislations, and third party voluntary sustainability certification schemes were further investigated in order to explore their potential consideration for the revised criteria, according to comments received from stakeholders.

As result, in **the second draft TR2.0** it was suggested to tentatively maintain the initially proposed criterion on "Origin and traceability of vegetable raw materials". However, several modifications were introduced:

- The requirements were further specified based on the sustainability requirements for the production of biofuels and bioliquids through the use of certified renewable raw materials including biomass as documented in the European Union Renewable Energy Directive and the criteria included in the different available schemes used to fulfil RED Directive.
- References to valid available certifications schemes that could be used for the assessment and verification of the proposed criterion were included in the text. In addition, other equivalent schemes which fulfil criteria to be complied with were suggested to be equally accepted.
- Finally, considering that the available schemes could be used for broad range of renewable raw material, and only for vegetable raw material, it was suggested to broaden the scope of the criterion to all types of renewable raw materials.

Moreover, to ensure the feasibility of the proposed criterion, stakeholders were asked to provide data on their practices with regard the use of certified renewable raw material.

- **Outcomes from and after the 2nd AHWG meeting**

During 2nd AHWG meeting some stakeholders expressed concern about how an additional criterion for renewable materials could affect the formulation of future products. Some

[56]http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014D0893&from=EN; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32012D0721

stakeholders expressed concerns about the limitations of the current certification schemes; for instance the limitation of the renewable energy directive (currently under revision); or those of the RSPO standard regarding some sustainability areas such as greenhouse emissions. Several stakeholders mentioned that small and medium-sized companies will not be able to meet the requirements of third-party certification schemes, as the process of certification is difficult and expensive.

The outcome from the European Union Ecolabelling Board (EUEB) meeting held in November indicated that some members supported the inclusion of certification schemes, but most of them argued that it was relevant only for palm oil and palm kernel oil and their derivatives. It was also stated that if a minimum percentage of certified material is required, it would be important to know to what extent current licences would be able to comply with it.

- **Further research and main changes in the third proposal**

From the feedback received, further research has been done to identify to what extent currently EU Ecolabelled products use certified renewable materials, in which percentage, and which certifications are the most commonly used in the sector.

To obtain this information, an on-line survey of 14 industrial stakeholders holding 127 of current EU Ecolabel licenses was carried out. Six responses were received:

- 5 out of the 6 industries do have / use certified sustainable renewable raw material.
- With regard to certification used, only third party certified and verified palm oil is used. Also two of them receive information on the source/origin of the materials from their suppliers.
- Regarding which minimum percentage should be required for certified raw material, 3 of the respondents defined a feasible percentage of 25%. The remaining respondents did not agree with setting a minimum percentage of certified renewable materials due to the immaturity of the market and certifications. According to responses, only a limited amount of renewable raw materials used in lubricants are certified. Therefore, setting percentage of certified material would limit the raw material base significantly and disqualify many products from the LuSC List.

Some additional comments from the survey respondents also include:

- Some manufacturers use certified palm oil under RSPO, but only as ingredient for other products such as personal care, but not for lubricants products.
- Manufacturers of biodegradable lubricants are dependent on suppliers of synthetic ester. Synthetic ester suppliers already offer products certified under current schemes of sustainable origin, and the part of certified raw materials may correspond to the part of renewable raw materials the product contains.
- Sustainability certification schemes for renewable raw materials are available on the market only for selected materials, such as palm oil. For many widely used raw materials in the EU Ecolabel products such as sunflower oil, coconut oil or tallow oil, and others, there are no such certificates on the market. There is also no dedicated supply chain to ensure that raw materials from different sources are not mixed during the value chain. So, it cannot be guaranteed that the certified raw material is actually in the final product carrying the label. Therefore, it is proposed to revisit this option during the next revision of the EU Ecolabel.

Considering all the feedback and comments received for the third proposal, the criterion has been maintained, but only keeping a minimum percentage of certified material for palm oil and

palm kernel oil as well as their derivatives, whereas only reporting procedure is requested for the rest of renewable materials.

According to the online survey addressed to industry with EU Ecolabelled products and other comments received from stakeholders as well as feedback from EUEB, requesting renewable materials to be certified under a third-party certification scheme is currently only feasible for palm oil and palm kernel oil as well as their derivatives. For the rest of renewable substances, more evidence of current and potential use of third-party certification in lubricant products is needed.

For the requirement for palm oil, the same wording included in other EU Ecolabel product groups such as detergents has been followed. Nevertheless, a percentage has been set based on suggestions from stakeholders who responded to the survey.

For the rest of renewable substances, this requirement would allow collecting information from industry during the implementation of this criterion. In addition, the requirement would also help to have a potential proposal on applicable third party schemes for lubricants in future revisions of the criteria set. However, in order to promote the use of certification schemes for all types of renewable ingredients used, it is suggested to allow the applicant to display this information on the EU Ecolabel. (See criterion 8: Information appearing on the EU Ecolabel)

Detailed information on the different existing certification schemes could be included in the User Manual. In addition to addressing the concerns expressed by several stakeholders, the User Manual should contain explanations about the certification procedures. It is the raw material supplier that needs to be certified, not the lubricant producer company. The lubricant producer should choose certified ingredient supplier in order to have certified ingredients.

In the other hand, the standard *"DIN CEN/TR 16227; DIN SPEC 51523:2011-10.Liquid petroleum products - Bio-lubricants - Recommendations for terminology and characterisation of bio-lubricants and bio-based lubricants"* includes information about bio-lubricants and recommendations for bio-lubricant (and biobased lubricant) related terminology. These recommendations are based on a discussion of commonly used terms in this field. This Technical Report also briefly describes the current test methods in relation to the characterization of biolubricants and the quantification of bio-based content.

In the third proposal, it was included an additional requirement for those cases where EU Ecolabelled products are bio-based. This will ensure that bio based lubricants are produced and marketed according to this standard, guaranteeing a good use of the term bio.
This requirement is aligned with the current criteria of Blue Angel.

- **Outcomes from last written consultation, Inter Service Consultation and final changes**

Majority of the comments received following the written consultation focused on the formulation of the criterion with particular reference to: percentage of certified palm ingredients, acceptable palm oil supply chain models, the "appropriate" use of the term "bio" with reference to applicable standard, and verification requirements. All received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Consequently, in response to some of the comments, the following modifications were introduced in the criterion text:

- The information reporting requirement was finally deleted as it is not an environmental performance requirement. The name of the requirement has been amended accordingly.

- A major change in the formulation of the criterion is the increase of the percentage of (w/w) of the palm oil renewable ingredients from 25% to 100%. Several Competent Bodies asked to increase the value to 100% in line with detergents product group. In addition, they mentioned that the number of available licences suggests that palm oil is not of relevance and hence requesting 100% certified palm oil ingredients would not significantly impact the number of available licences, the increase to 100% is considered feasible. Several licence holders have been further contacted with this regards. Although a manufacturer prefers to have a flexible requirement (keeping the 25% proposal), another manufacturer considered it easier for them to manage their supply chain and manufacturing with the value set at 100%.

- Another change was the amendment as suggested by stakeholders to refer to the recent "*EN 16807:2016*" instead of the "*CEN/ TR 16227:2011* ".
- Minor wording format changes have been introduced**.**

Some changes were also made to the **assessment and verification** text.

- Equivalent test methods for sub-requirement b) have been included as suggested by stakeholders.
    - EN 16785-1:2015 [Bio-based products - Bio-based content - Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis]
    - EN 16640:2017 [Bio-based products - Determination of the bio-based carbon content of products using the radiocarbon method]

  Other equivalent methods are accepted as specified in the general assessment and verification text for each EU Ecolabel Decision. Therefore the text "other equivalent methods" has not been repeated in this specific section.

- A significant change was made to the wording of the text to reflect the changes made to the RSPO supply chain models as of 1st January 2017, when RSPO Credits replaced GreenPalm certificates, and also the market situation where derivatives of palm oil and palm kernel oil used in oleochemical and chemical industries are mostly sold via the book and claim supply chain model. Consequently, the amended text reads" *For palm oil and palm kernel oil derivatives, the amounts of RSPO credits purchased and claimed in the RSPO PalmTrace system model during the most recent annual trading period shall be provided to demonstrate compliance to the Book and Claim supply chain model".*

3.6 CRITERION 5: Packaging requirements

Final proposal for criterion 5: Packaging/container requirements

Final proposal for criterion 5: Packaging/container requirements

a) Recycled content (applicable only in the case of lubricants sold in plastic packaging/container): plastic packaging/container shall be made of a minimum of 25% of post-consumer plastic.

b) Design (applicable only in the case of lubricants designed to be sold to private end consumers): the packaging/container should have an appropriate system (e.g. prolongation systems or narrow apertures) in order to avoid spillage during use.

Assessment and verification

The applicant shall provide the following evidence as applicable:

The composition of the plastic packaging/container and the shares of recycled and virgin material. If necessary, a declaration of compliance from the plastic packaging/container supplier shall be included.

Post- consumer plastic means plastic generated by households or by commercial, industrial and institutional facilities in their role as end-users of the product which can no longer be used for its intended purpose. This includes returns of plastic from the distribution chain.
Post-consumer plastic content shall be calculated as shown below. As there are no methods available for directly measuring the recycled content in a product or packaging, the mass of plastic obtained from the recycling process, after accounting for losses and other diversions, shall be used.
X(%)= A/P x 100
Where:

X is the (post-consumer) recycled content
A is the mass of the recycled (post-consumer) plastic
P is the mass of the packaging/product

A description of the design of the packaging/container, along with photos or technical drawings, shall also be provided.

Rationale of proposed criterion text

Earlier this year European Commission has published the European strategy for plastics in a circular economy[57] where one of its aims is to boost the uptake of the recycled plastics and also create the market for this type of plastics. In line with the objectives of the strategy for plastics, the criteria should also seek to facilitate the transition to a more circular economy by encouraging improved design and by further incentivising the demand for recycled materials by introducing the requirement of recycled content in the packaging of lubricants that is also beneficial for the image and CSR of the companies that are producing the EU Ecolabel lubricants due to the constantly increasing public awareness to this topic. The relative impact generated for the packaging is minor compared to the lubricant manufacturing and other stages, while the public and legislative pressures are increasing. Moreover recycled content has a substantial impact on CO_2 emissions. Replacing virgin material with recycled results in even up to 80% emissions reduction.

[57] COM/2018/28 final

At least one regional eco-label includes information about the design of the packaging: NF-Environment includes a criterion on design to prevent the retention of the lubricant and also for the right dosing of lubricants.

In the **first proposal**, different requirements were included in the criterion text, e.g. referring to the design of the dispenser closure. Two proposals were presented for a consultation with stakeholders: the inclusion of recycled content in the packaging design and the recyclability of the packaging.

After the first consultation, a different approach was introduced in the criterion. In the **second proposal** a differentiation between B2C and B2B products was introduced. According to stakeholders, approximately 95% of the EU Ecolabel lubricants are B2B products and normally are delivered as:

- Small packs, suitable for small volumes of lubricant (up to 10 L) and or infrequent use.
- Pails, can be made from plastic or steel, usually in the range 5-25 kg. These are best for handling, small volume use and limited space / staking is required.
- Drums, where large volumes of lubricant supply are required. The 55 gallon drum is the most frequently used in the industry. These are best for constant consumption. A full drum can usually weight 204 kg.
- Bulk, for high-volume requirements and operations suited to piped supplies of lubricants. A bulk-storage vessel installed on site offers the most efficient and convenient solution.

In the second criterion draft it was proposed to delete the requirement on recyclability, since a lubricant package contaminated with the product, is classified as a dangerous package. The criterion referring to the packaging closure was maintained in order to avoid accidental spillages. The requirement on the recycled content was maintained and extended also for B2B products. An initial minimum of 25% of recycled content was suggested. In addition, in order to promote the circularity of B2B products it was suggested to discuss the possibility to set a criterion to require applicant to provide take back systems for such products.

- **Outcomes from and after the 2nd AHWG meeting**

Different comments were received during the 2nd AHWG meeting and the consultation. The most controversial issues were the take-back system and the recycled content of the packaging.

Stakeholder pointed out that take-back systems are not extensively used in lubricant sector. Difficulties for developing a take-back system common for all the lubricant industries and the assessment of the methods used were identified as difficult by stakeholders.

On the other hand, stakeholders agreed to include a requirement about recycled content. However, the 25% of recycled plastic was not welcomed.

A clarification on the differentiation between B2B and to private end consumers was asked.

Finally, during the 2nd AHWG meeting, some stakeholders suggested to include a requirement concerning the presence of SVHCs in the packaging.

- **Further research and main changes in the third proposal**

Taking the comments and discussions into account, the criterion has been modified. First of all, the take-back system requirement has been deleted. Different stakeholders have been consulted to provide feedback about their practices with this regards. Responses from them show that it is not common to implement take-back systems for B2B lubricant packaging/containers: 14

stakeholders were consulted, and only 5 responses were received about take-back system: 3 of them answered that they do not have a take-back system for packaging waste. Currently, there is no harmonized European take-back system for packaging of lubricants. However, one response was received from a stakeholder remarking that in B2B containers are repeatedly cleaned and reused. Other stakeholders pointed out that *in Germany an "indirect" take-back system for steel drums exists but only for sales within the German market. If products are sold outside of Germany the drums or plastic containers will be sold as well and belong to the customer. Of course we as a manufacturer who wants to sell our products world-wide cannot guarantee a take-back system for other regions of the world.*

Most of the stakeholders did not see it feasible to include a requirement on a take-back system (4 of 5 responses) and in consequence this proposal was dropped.

The rest of the elements of the criterion are kept with minor clarifications on the wording.

In relation to the percentage of recycled material for plastic packaging/container, the Article 11 of Directive 2008/98/EC defines a target to ensure a high level of resource efficiency: by 2020, the preparing for re-use, recycling and other material recovery shall be increased to a minimum of 70 % by weight[58]. This ambitious target supports the inclusion of a minimum recycled content requirement.

Stakeholders have been consulted regarding the percentage of recycled content in packaging. Even though there are manufacturers that include a percentage of recycled content in their packaging, 4 of the 5 responses of stakeholders coincide in the deletion of this requirement because they agree that the criterion is not feasible. One stakeholder pointed that for some kind of packaging it is even not possible to use recycled materials.

Mandatory plastics recycled content in the EU Ecolabel for packaging and for specific applications is an important tool to boost the uptake of recycled materials in Europe. Lubricants packaging is predominantly made from HDPE. Recycled HDPE is already used in packaging of cleaning products in content above 20 %; there are even companies that are using packaging that has 80% of the recycled content inside[59].

There is a study on development of recycled HDPE for cleaning products packaging which analyses handle free bottles design with different recycled content (0%, 50% and 100%) show no major differences in properties (traction and compression mechanical properties, chemical resistance) between the virgin only and bottles with recycled content.

Although lubricants may require slightly different packaging properties than cleaning products, that shall not constitute an obstacle for recycled content uptake. For more demanding products, a double or even triple layer can be used with 20% or even higher recycled content. Additionally, there are no technological barriers for producing packaging bottles of 20 or 25 liters with recyclates[60].

This criterion is considered relevant in terms of the circular economy and the image of the EU Ecolabel companies, the level proposed is quite conservative and no technical evidence of existing limitations has been received. Therefore, the requirement is suggested to be kept.

- **Outcomes from last written consultation and final changes**

[58] DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0098&from=EN
[59] Aimplas: Development of recycled HDPE for cleaning products packaging. 2017
[60] Aimplas: Development of recycled HDPE for cleaning products packaging. 2017

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this criterion as a result of the final consultation:

- In order to avoid misunderstandings and misinterpretations, it is proposed to reword the text and to eliminate the word DISPENSER (since it may wrongly refer to an extra component allowing dosing).

Rationale of proposed assessment and verification

Minor changes have been introduced in the assessment and verification section for the second proposal. The documents needed to verify the criterion have been differentiated according to different requirements.

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this assessment and verification as a result of the final consultation:

- Usage of terms and evaluation methodology with regards recycled content included in ISO 14021:2016 Environmental labels and declarations -- Self-declared environmental claims (Type II environmental labelling) has been reflected in the text.

3.7 CRITERION 6: Minimum technical performance

Final proposal for criterion 6: Minimum technical performance

The lubricant product shall comply with the corresponding minimum technical performance requirements as specified in Table 5.

Table 5. Minimum technical performance for lubricant products

Lubricant category	Minimum technical performance
Chainsaw oils	KWF test version 2017 test or equivalent
-Wire rope lubricants -Concrete release agents -Other total loss lubricants -Stern tube oils -Metalworking fluids	"Fit for purpose" demonstrated by at least one "applicant's clients approval"
Gear oils	gear oils (closed gears): ISO 12925-1 or DIN 51517 section (I, II or III) gears oils (open gears): "Fit for purpose" demonstrated by at least one "applicant's clients approval".
2-stroke oils	2-stroke marine: NMMA TC-W3 2-stroke terrestrial: ISO 13738 (EGD)

Final proposal for criterion 6: Minimum technical performance

Hydraulic systems	ISO 15380 (Tables 2 to 5) Fire resistant hydraulic fluids: ISO 15380 (Tables 2 to 5) + ISO 12922 (Table 1 to 3) or Factory Mutual Approval
	"Fit for purpose" demonstrated by at least one "applicant's clients approval".
Temporary protection against corrosion	ISO/TS 12928:1999 or "Fit for purpose" demonstrated by at least one "applicant's clients approval".
Lubricating greases	Greases for temporary protection against corrosion: ISO/TS 12928or "Fit for purpose" demonstrated by at least one "applicant's clients approval". Greases for closed gear: DIN 51826 Greases for roller bearings, plain bearings and sliding surfaces: DIN 51825 All other greases: ISO 12924 or "Fit for purpose" demonstrated by at least one "applicant's clients approval"

Note: Multipurpose greases that include any of the above specified applications among their potential uses shall be tested according to the corresponding specific test of the relevant specified application.

***Assessment and verification*:** the applicant shall provide a declaration of compliance with this criterion supported by testing results, where appropriate.

For hydraulic systems, it shall be indicated on the product information sheet which elastomers have been tested.

Applicant's clients approval means a letter/document/statements issued by clients for a specific product, assuring that the product met their specifications and works correctly in its intended application.

Rationale of the proposed criterion text

In the first proposal it was suggested to incorporate a technical performance criterion for the new categories suggested to be included in the scope, as 4-stroke engine oils or metalworking fluids. Moreover, some categories that are currently considered in the EU Ecolabel were revised in order to establish a minimum technical performance that brings additional protection to the EU Ecolabel as a quality seal. However, minimum stability requirements (MSR) suggested for some lubricant types in the first proposal, does not have technical performance standard associated with the product families, and could be ambiguous. Therefore, in the second revision, minimum stability requirements had been replaced for "at least one relevant **OEM approval**".

a) Total loss systems

For chainsaw oils the existing EU Ecolabel technical performance in force is based on RAL UZ 48. There are, however, other eco-labels, as NF Environment brand, that are based on other standards as AFNOR 375-0 (certification scheme criteria 7 to 12). In addition, ISO/TC 23/SC 17 has recently defined a new test procedure to evaluate the chainsaw oil lubrication ability, ISO/TS 19858:2015. Therefore, for the first proposal it was suggested to keep RAL UZ 48 and

to include AFNOR NF 375 standard for chainsaw lubricants. In the second revision, considering the updated information with regard KWF-Test (version 2 – June 2016) and RAL-UZ 48 basic award criteria document, which since June 2016 is called RAL-UZ 178 it was suggested that the new KWF-Test from June 2016 describing test for chainsaw oils should be assessed thoroughly. The main functions of wire rope lubricants are not only to reduce friction as the individual wires move over each other, but also to provide corrosion protection and lubrication in the core, inside wires, and on the outer surface. In the first revision the minimum technical performance was suggested based on common analysis. Although due to the lack of standards, it was suggested to change the requirement to "at least one relevant OEM approval" in the second revision.

For other TLL, as railway lubricants, a minimum stability requirement (MSR) was proposed, which guarantees no aspect changes for a short storage time, although for several types technical performance criteria are desired. However, after the first consultation, it was agreed that minimum stability requirements (MSR) defined in some categories (other TLL or metalworking fluids) were not well defined. Due to the importance of having good performance products on the market, it was considered necessary to request "at least one relevant **OEM approval**" for other not specified TLL (e.g. wire ropes).

b) Concrete release agents

With regard to concrete release agents, after completing a deep review, no technical standards were found that cover minimum technical performance. Other ecolabel programs also lack a specific technical performance requirement. As a result, it was decided to propose "at least one relevant OEM approval".

c) Gear lubricants

Existing EU Ecolabel requirement in force for gear lubricants, as well as other ecolabel like the Swedish Standard, take the recognized DIN 51517 specification as a basis to define a minimum technical performance. In addition, the standard ISO 12925 has also been taken into consideration as an alternative standard. As a result, for the first proposal it was suggested to keep the existing minimum technical performance criterion (DIN 51517 (I, II or III)).

In the second revision gear lubricants have been distinguished in open gears and close gear, preserving the DIN 51517 for enclosed gear oils. For open gear it was suggested "at least one relevant OEM approval".

d) Internal combustion engine oils

Internal combustion engine oils were classified in: 2-stroke and 4-stroke engine oils. The existing EU Ecolabel technical performance for 2-stroke engine oils was not been modified for the first proposal. In addition, 4-stroke engine oils have been removed from this revision.

e) Hydraulic systems

Existing EU Ecolabel in force as well as Swedish Standard for hydraulic fluids are both referring to the ISO 15380 standard. In the first proposal, the minimum technical performance was maintained. Nevertheless, only for fire-resistant hydraulic fluids (not the rest of hydraulic fluids) it was suggested to meet some additional requirements and pass several fire resistance tests.

As many end-users require the factory Mutual Approval and to prevent an extra effort, it was suggested that the applicant could provide a declaration of compliance with the Factory Mutual Approval Standard 6930 or perform the criteria of ISO 12922, Table 1 to 3. Following ISO 12922, there are different limit values according to categories for:

- ISO 14395 - Wick test: Mean flame persistence

- ISO 20832 - Hot Manifold test: Ignition temperature
- ISO 15029-1 or ISO 15029-2 - Spray ignition: Excluded from the minimum technical performance

f) Metalworking fluids

No other ecolabels include technical performance criteria for MWF. Considering the variety of products and applications for this new category with diverse performance requirements, "at least one relevant OEM approval" was proposed, although for several types technical performance criteria are desired.

g) Temporary protection against corrosion

No other ecolabels include technical performance criteria for this new family group, it was proposed for the first proposal to, at least, the lasting of the corrosion protection complies with what defined in ISO/TS 12928:1999 "Lubricants, industrial oil and related products (class L) – Family R (Products for temporary against corrosion) – Guidelines for establishing specifications", (Table 1 to 3). This standard is a guideline that establishes specifications for temporary corrosion protection products for a given application that is required for end user's evaluation.

h) Stern tube oil lubricants

In the first proposal, stern tube oil lubricants were suggested to comply with the limits of ISO 8068:2006. However, the wide range of applications including circulating oil, hydraulic oil, gear oil, among others, makes ISO 8068:2006 not necessarily appropriate for stern tubes lubricants. Therefore, for the second proposal it was suggested that "at least one relevant OEM approval" is required.

i) Lubricating greases

Existing requirement in force specify 'fit for purpose' as a minimum technical performance. Other eco-labels schemes (Swedish Standard, Japan Ecolabel) establish several requirements for greases, different from "Fit for purpose". The Swedish Standard, similar to ISO/DIS 12924, classifies greases according to their properties: the lower and upper operating temperature; gel strength (oil separation); corrosion preventive abilities of lubricating greases; and lubrication ability under extremely high loads. Some requirements that grease should fulfil according to the Japan Ecolabel include the dropping point, the penetration, the oil separation and the water wash-out, to name only the most common ones.

Such a wide range of applications for greases, ranging from lubrication in industrial, automotive or marine use, makes very difficult, if possible at all, to establish a clear technical requirement for greases. Quite often grease does not need to fulfil specific technical standard in order to properly perform its functional requirements.

In the first proposal it was suggested to ask for temporary protection against corrosion grease to fulfil the specifications of performance duration of ISO/TS 12928:1999; and for gear greases to fulfil the requirements of DIN 51517. For stern tube greases stern tube greases minimum technical performance was maintained in the form of "fit for purpose" (under 'other greases').

After the first meeting, it was agreed to modify gear greases minimum technical requirements. It was proposed that DIN 51826 for closed gear boxes greases and DIN 51825 for greases in roller bearings, plain bearings and sliding surfaces are used. For other gear applications, such as open gear greases, it was suggested a "fit for purpose" criterion as in the existing EU Ecolabel.

It was also noted that there were overlaps, and it was difficult to know to which class some of the products are assigned. For multipurpose grease, the minimum technical requirements are aligned with its applications. For example, if the grease is suitable for wire and corrosion, it shall perform ISO/TS 12928:1999. Another example, if multipurpose grease is suitable for bearings and gears, it shall perform according to DIN 51825 and DIN 51826, respectively. If it does not perform appropriately, this could mean that is not suitable for the application. A note to reflect these potential situations has been included.

- **Outcomes from and after the 2nd AHWG meeting:**

During the second consultation, one stakeholder suggested that having commercial sales of a product for a specific application should be enough prove that the product complies with a minimum performance. A stakeholder asked if it was possible in the criteria to use 'case studies' based on market experience, which are suitable to prove compliance.

In relation to chainsaw oils, several stakeholders expressed concern related to the reference to RAL-UZ 178. It could be misinterpreted by testing laboratories leading to the testing of all RAL requirements. Specific reference only to KWF guidelines was asked instead.

In addition, it was mentioned that the ISO/TS 12928:1999 does not cover specific requirements but only contains guidelines for establishing specifications. A stakeholder wondered if the requirements should be examined separately with a view to a common agreement between the end user and the product supplier.

- **Further research and main changes in the third proposal**

Only small changes in minimum technical performance have been made, i.e. for chainsaw oils it has been specified that the requirements that must fulfil are KWF guidelines as requested by stakeholders. Reference on where to find the guidelines (currently posted in EU Ecolabel website) will be included in the User Manual.

Moreover, it has been added an alternative standard for enclosed gear boxes besides DIN 51517, the ISO 12925.

Additionally, considering stakeholder comments, the "fit for purpose" requirement has been reintroduced for several categories where no available testing methods exist. A preference to proof the "fit for purpose" via the "OEM approval" has been reflected in the text.

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this criterion as a result of the final consultation:

- Most recent version of KWF has been specified. English version will be available in DG ENV website at the adoption date of the criteria.
- In order to avoid issues with regard the lack of repeatability and reproducibility of other methods than ISO or EN it has been added the possibility to demonstrate compliance with ISO/TS 19858"Forestry machines -- Portable chain-saws -- Test method for evaluating saw chain oil lubricity"
- Considering the confusion surrounding the OEM approval, fit for purpose has been amended to include *applicant's clients approval*, in line with existing guidance (current UM).

Rationale of proposed assessment and verification

In the second proposal a minor modification in the assessment and verification section was included to reflect that the technical criteria for hydraulic fluids based in the standard ISO 15380 includes an elastomer compatibility test, where at least two elastomers types shall meet the specifications. Therefore, as is specified in the existing text in force, it should be indicated on the product information sheet, which elastomers have been tested.

In addition, in order to give flexibility and minimise the costs of the testing it was suggested to allow the following verification options: manufacturer's own laboratory which has a quality assurance system encompassing sampling and analysis and has been certified according to ISO 9001 or ISO 9002 or independent third party testing laboratories.

- **Outcomes from and after the 2nd AHWG meeting:**

During the second consultation, assessment and verification methods were discussed. It was mentioned manufacturer's own laboratory which has a quality assurance system or independent third party testing laboratories should be used to check the compliance with the requirements. Some stakeholders said that the third party testing laboratory has to be certified according to ISO 17025.

- **Further research and main changes in the third proposal**

In the third revision, it was decided that in order to run tests to prove compliance on a specific technical performance, only reports from third party independent accredited laboratories should preferentially be accepted as requested in the general assessment and verification text.

Commercial sales of a product are an internal prove, which cannot be certified by a third party; and it would also be very difficult to stablish a threshold for sales value, for SME, for larger companies; this is a good internal indicator, only.

For those categories where "fit for purpose" is requested, it shall be demonstrated preferentially trough "at least one OEM approval". In the absence of OEM approval, it is suggested that test report is provided.

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this assessment and verification as a result of the final consultation:

- Definition for *applicant's clients approval* has been included.

3.8 CRITERION 7: Consumer information regarding use and disposal

Final proposal for criterion 7: Consumer information regarding use and disposal
In the case of lubricants designed to be sold to private end consumers, the following information (in text form or pictograms) shall be present on the packaging/container (comparable text formulations are permitted): "Avoid any spillage of unused product to the environment", "Product residue and package/container shall be disposed in dedicated collection points".

Final proposal for criterion 7: Consumer information regarding use and disposal
***Assessment and verification*:** the applicant shall provide a sample of the product container/packaging or its artwork where the above information appears.

Rationale of proposed criterion text

The European List of Waste (Commission Decision 2000/532/EC[61]) classifies wastes and provides a common terminology to improve the efficiency of waste management activities. Lubricating oils are included in the category 13: Oil wastes and wastes of liquid fuels.

Waste oils can have high negative environmental impact if they are not collected correctly but released to the environment. The uncontrolled disposal could affect soils, aquatic life and renders water unfit for consumption.

A criterion to ensure the proper disposal of waste lubricant is important to decrease the overall environmental impact, especially in aquatic ecosystems.

Disposal of waste lubricant is a criterion considered in different ecolabels. Most of them consider the inclusion of a description with the information about the waste disposal. Some references are:

- Nordic Swan: Lubricating oils must be delivered to an approved site or collector of toxic waste.
- NF-Environment: All lubricating oils can present a risk to the environment and health and therefore should not be discharged into sewers, water or soil.
- Swedish Standard specifies that the waste lubricant must not discharge into drains, water courses or onto the ground; and that the applicant should provide recommendations for safe handling of lubricant. It introduces a new specification concerning the emergency plan in case of spillage.

The industry should put in place mechanisms to make available appropriate disposal and separation facilities. In case of the private consumers, the disposal of the lubricant cannot be controlled and regulated; nevertheless the use of lubricant presents higher risk due to the lack of knowledge of the consumer. For this reason, the applicants shall inform product end users on how to properly dispose of used lubricant.

Against this background a new criterion was proposed in the first technical report: *Criterion 9 (New): Consumer information regarding use and disposal.* The criterion alerts about the lubricant risk in case of ending up in the environment.

During the first consultation the relevance of the criterion was questioned considering the number of products certified B2C. However, the same product licence may include a broad range of products with different market availability. Considering that a certified product could be sold in private end consumer format, the criterion was maintained.

Other relevant statements used in other EU Ecolabels and national Ecolabels were consulted to identify alternatives to the first proposal. Blue Angel includes a criterion for lubricants designed to be sold to private end consumers (more information in TR2.0).

In the first proposal, the following sentence was suggested: *Lubricating oil may be harmful to health and environment*. After the first revision this sentence was modified because it was

[61] Commission Decision 2000/532/EC: European List of Waste

questioned by stakeholders. The sentence included information about the health and environmental risk contradicting with Criteria 1, 2 and 3 of the EU Ecolabel.

Moreover, in the second revision, the sentence was complemented with the following statement: "..., therefore be mindful and avoid any spillage to the environment".

- **Outcomes from and after the 2nd AHWG meeting**

Some stakeholders did not support to include the last part of the sentence "Product residue must be managed by an authorized waste manager" because it is covered with other regulatory requirements. Other comments were referring to the first part of the sentence, since it could be confusing having in mind that the requirement of excluded or limited substances is established.

- **Further research and main changes in the third proposal**

With the purpose of making this criterion more understandable, the first part of the sentence has been partially modified. Modifications have been done considering the Blue Angel scheme. Moreover, the new text can be substituted by pictograms.

On the other hand, a proposal made by one stakeholder has been included in the criterion text as an alternative to "managed by an authorized waste manager".

- **Outcomes from last written consultation and final changes**

Received comments and the respective answers can be consulted in the ANNEX I. Table of comments. Following minor changes have been introduced in within this criterion as a result of the final consultation:

- A stakeholder mentioned that "Avoid any spillage to the environment" seems strange as lubricant is released (to certain extent) into the environment when used. The test has been reworded: "Avoid any spillage of unused product to the environment".

3.9 CRITERION 8: Information appearing on the EU Ecolabel

Final proposal for criterion 8: Information appearing on the EU Ecolabel
The optional label with text box may contain the following text: a) "Less hazardous substances ending-up in the environment", b) "Verified performance" c) "X% of certified renewable ingredients used" (where relevant)", The guidelines for the use of the optional label with text box can be found in the 'Guidelines for the use of the EU Ecolabel logo' on the website: http://ec.europa.eu/environment/Ecolabel/promo/logos_en.htm *If certified renewable ingredients are used, regardless of the type of biomass (e.g. rapeseed, sunflower, palm, soy, etc…), total content of certified ingredients can be indicated. ***Assessment and verification:*** The applicant shall provide a sample of the label. If statement c) is used, the applicant shall provide the relevant certificate(s) related to the percentage of certified renewable ingredient(s) used.

Rationale of proposed criterion text

According to Article 8 (3b) of the EU Ecolabel Regulation 66/2010, for each product group, three key environmental characteristics of the EU Ecolabel product may be displayed in the optional label with text box. The guidelines for the use of the optional label with text box can be found in the "Guidelines for the use of the EU Ecolabel logo" on the website[62].

Information about the EU Ecolabel on the product helps to inform the consumer on the environmental preference of this product and make easy the environmental friendly decision. For this reason this criterion is included in all EU Ecolabels.

A first proposal was done partially modifying the information that appears on the existing EU Ecolabel criterion. Main change corresponded to the deletion of the claim *contains a large fraction of bio-based material* that would not be always the case regarding the proposal made for the first AHWG to introduce other base oils in criterion 4. In addition, for the first proposal it was suggested to introduce the claims:

- *Restricted amount of hazardous substances;*
- *Tested for lubricating performance*

Also instructions on the use of logo and license number and the general text were aligned with the recently voted detergents product group.

After the 1st AHWG meeting, some modifications were introduced in the criterion text:

- As suggested by stakeholders, the wording of "*Restricted amount of hazardous substances*" was modified by "*Limited amount...*" and the sentence was merged with existing text in force related to the impact on water and soil.
- The sentence "*Tested for lubricating performance*" was modified considering that not all products covered under the scope are tested. In the 2nd Technical Report two options were presented to discuss with stakeholders: "*Verified performance*" and "*As effective as the average product on the market*".

- **Outcomes from and after the 2nd AHWG meeting**

Few comments were received about this criterion. The options presented by JRC were discussed, stakeholders agreed to delete the second part of the sentence, because is not attractive for consumers.

- **Further research and main changes in the third proposal**

Minor changes have been introduced in the criterion. Main change corresponds to the inclusion of an additional sentence in order to allow the applicant to display the % of certified renewable ingredients, when used. This will promote the use of certified ingredients.

This was seen as a first step in the absence of a prescriptive requirement on a minimum sourcing of certified ingredients for this revision. The lack of data and the absence of mature schemes to verify the sustainable sourcing of all type of renewable ingredients were the main reasons behind the unfeasibility to set a prescriptive requirement.

[62] http://ec.europa.eu/environment/ecolabel/documents/logo_guidelines.pdf

- **Outcomes from last written consultation and final changes**

Sentence "Reduced harm for water and soil during use due to limited amount of hazardous substances" has been reformulated. Consultation to ECHA revealed that the new text would be more appropriate in terms of CLP compliance. No additional changes as has been introduced as a result of the last written consultation. Detailed comments/responses in the ANNEX I. Table of comments.

In addition it has been added a note to clarify that the sentence “X% of certified renewable ingredients used” could be used regardless of the type of biomass.

4 IMPACT OF CHANGES TO CRITERIA

This section consists of a summary of the main general changes proposed for the revised criteria and potential implications for current license holders and possible applicants.

In relation to the **scope** there are two main aspects proposed:

- Enlargement of the scope to cover a higher market share and classification of the lubricants into three main categories: Total loss, Partial loss, and Accidental loss (ALL, PLL, and TLL), depending on the risk to be released to the environmental. This lead to the unification of the previous categories 1 and 5 by ALL – Accidental Loss Lubricant, and categories 2 and 4 under PLL – Partial Loss Lubricant has been. The previous category 3 has been assigned to TLL – Total Loss Lubricant.

- In addition, in order to better define the covered categories, a definition for each category has been included in the complementary definitions section. In the case where an ISO (ISO 6743 "Lubricants, industrial oils and related products") family has been developed for a specific category, a reference to it has been included in the definition text

These two aspects have direct implications on possible applicants due to a wider and clearer scope. There is a broader spectrum of lubricants that can be awarded with the EU Ecolabel and in addition it is clearer to understand which different types of lubricants are covered by the scope.

In relation to the **criteria,** there is a general raise of ambition level proposed, based mainly on the results of the analysis of data received from competent bodies and information from other labelling schemes.

Regarding the criteria dealing with excluded or limited **hazardous substances, aquatic toxicity, bioaccumulation and biodegradability of products (criterion 1, 2 and 3),** the requirements have been modified considering changes in legislation, new evidence and data from current EU Ecolabel licences. One of the main changes corresponds to **criterion 1**. In order to apply a strict interpretation of the EU Ecolabel Regulation, it is proposed to restrict the EU Ecolabel hazards at substance level as per regulation as made in other product groups. It was proposed to eliminate the general derogation to the lowest classification limit that would trigger the classification of the final product and to propose a higher degree of flexibility, exceptionally, only for substances classified with specific hazard statements that currently would not comply with the horizontal 0.01%. The following issues were taken also into account:

- **Hazard groups 1, 2 or 3**, i.e., prioritization based on the grouping of hazards as per the EU Ecolabel Chemicals Task Force
- **Impact on the LuSC-list** (high, medium or low)
- **Impact on current licenses** (high, medium or low)

Based on the analysis conducted, the following thresholds have been proposed:

- For substances included in **Group 3**: **Maximum total concentration that is smaller than the concentration that would lead to classification of the final product.** As in the existing limit currently in force.
- For substances included in **Group 2 and medium/high impact on LuSC-list/ current licenses**: **maximum of half of the relevant concentration that would lead to classification of the final product** in the specific hazard class.
- For substances included in **Group 2 and low impact on LuSC-list and current licenses**: Concentration limit < 0.010 % weight by weight per substance in the final product according to the horizontal approach for other product groups.

With regard to **criteria 2 and 3**, the ambition level has been partially raised based on the analysis of the data collected. Data on 143 EU Ecolabelled products from 11 different countries was obtained. According to the analysis performed (for 40% of the existing licenses) the majority of the assessed licenses would be able to comply with the revised thresholds.

These changes reflect the evolution of the market and the industry, evolving to more sustainable and less hazardous products.

The existing criterion about raw materials has been deleted. The focus has been broad from vegetable oils/substances to other base fluids capable to comply with the requirements defined in criteria 1, 2 and 3. In recent years, technology developments allowed for increase of the quality of synthetic oils for several applications. For this reason they could be included in the new scope. With this change proposed, manufacturers have more alternatives to choose from, still complying with new, more restrictive thresholds proposed.

Regarding raw materials of renewable origin, a new criterion (criterion 4: Origin, traceability and advertising of renewable ingredients) has been included in this revision. In the case of bio-based lubricants, a minimum percentage of certified material for palm oil and palm kernel oil as well as their derivatives is requested (when palm oils is used as ingredient), whereas only reporting procedure is requested for the rest of renewable materials.

Two new criteria have been formulated for the **use phase and end-of-life,** since in LCA studies it was found that these two life stages can have important impacts associated. **Criterion 5** has been proposed for packaging including specifications about the packaging design to ensure a proper dosage of product. Also percentage of recycled content in packaging materials is asked for plastics. Further, a criterion about consumer information regarding use and disposal (**criterion 7**) has been included with information about how to manage the residual product and packaging at end of life of the lubricant.

Regarding the use phase, **minimum technical performance (criterion 6)** has been revised taking into account updated standards and new tests methods available.

Finally, **criterion 8** (information appearing on the EU Ecolabel) has been updated in line with the proposed criteria, with minor changes.

APENDIX I. EXISTING CRITERIA

Criterion 1 – Excluded or limited substances and mixtures

(a) Hazardous substances and mixtures

According to the Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel, the product or any part of it shall not contain substances (in any forms, including nanoforms) meeting the criteria for classification with the hazard statements or risk phrases specified below in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (1) or Council Directive 67/548/EEC (2) nor shall it contain substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (3). The risk phrases below generally refer to substances. Nanoforms intentionally added to the product shall prove compliance with this criterion for any concentration.

List of hazard statements and risk phrases:

Hazard Statement (4)	Risk Phrase (5)
H300 Fatal if swallowed	R28
H301 Toxic if swallowed	R25
H304 May be fatal if swallowed and enters airways	R65
H310 Fatal in contact with skin	R27
H311 Toxic in contact with skin	R24
H330 Fatal if inhaled	R26
H331 Toxic if inhaled	R23
H340 May cause genetic defects	R46
H341 Suspected of causing genetic defects	R68
H350 May cause cancer	R45
H350i May cause cancer by inhalation	R49
H351 Suspected of causing cancer	R40
H360F May damage fertility	R60
H360D May damage the unborn child	R61
H360FD May damage fertility. May damage the unborn child	R60; R61; R60-61
H360Fd May damage fertility. Suspected of damaging the unborn child	R60-R63
H360Df May damage the unborn child. Suspected of damaging fertility	R61-R62
H361f Suspected of damaging fertility	R62
H361d Suspected of damaging the unborn child	R63
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child	R62-63
H362 May cause harm to breast fed children	R64
H370 Causes damage to organs	R39/23; R39/24; R39/25; R39/26; R39/27; R39/28
H371 May cause damage to organs	R68/20; R68/21; R68/22
H372 Causes damage to organs through prolonged or repeated exposure	R48/25; R48/24; R48/23
H373 May cause damage to organs through prolonged or repeated exposure	R48/20; R48/21; R48/22
H400 Very toxic to aquatic life	R50
H410 Very toxic to aquatic life with long-lasting effects	R50-53
H411 Toxic to aquatic life with long-lasting effects	R51-53
H412 Harmful to aquatic life with long-lasting effects	R52-53
H413 May cause long-lasting harmful effects to aquatic life	R53
EUH059 Hazardous to the ozone layer	R59
EUH029 Contact with water liberates toxic gas	R29
EUH031 Contact with acids liberates toxic gas	R31
EUH032 Contact with acids liberates very toxic gas	R32
EUH070 Toxic by eye contact	R39-41

This criterion shall also apply to the following hazard statements and risk phrases:

Hazard Statement (6)	Risk Phrase (7)
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled	R42
H317: May cause allergic skin reaction	R43
H314 Causes severe skin burns and eye damage	R34; R35
H319 Causes serious eye irritation	R36
H315 Causes skin irritation	R38
EUH066 Repeated exposure may cause skin dryness or cracking	R66
H336 May cause drowsiness and dizziness	R67

Substances or mixtures which change their properties upon processing (e.g. become no longer bioavailable, undergo chemical modification) so that the identified hazard no longer applies are exempted from the above requirement.

Concentration limits for substances meeting criteria of Article 57(a), (b) or (c) of Regulation (EC) No 1907/2006 shall not exceed 0,010 % (w/w). If specific concentration limits are referred to for substances meeting criteria of Article 57(a), (b) or (c) they should remain below one tenth (1/10) of the lowest specific concentration value indicated unless this value falls below 0,010 % (w/w).

Derogations from Criterion 1(a) are listed in Table 1.

Assessment and verification of criterion: the applicant shall provide the exact formulation of the product to the competent body. The applicant shall demonstrate compliance with this criterion for substances in the product on the basis of information consisting as a minimum of that specified in Annex VII to the Regulation (EC) No 1907/2006. Such information shall be specific to the particular form of the substance, including nanoforms, used in the product. For that purpose, the applicant shall provide a declaration of compliance with this criterion, together with a list of ingredients and related Safety Data Sheets in accordance with Annex II to Regulation (EC) No 1907/2006 for the product as well as for all substances listed in the formulation(s). Concentration limits shall be specified in the Safety Data Sheets in accordance with Article 31 of Regulation (EC) No 1907/2006.

Sufficient data shall be available to allow for the evaluation of the environmental hazards (indicated by the hazard statements H400 – H413 or R-phrases: R 50, R 50/53, R 51/53, R 52, R 52/53, R 53), of the product in accordance with Regulation (EC) No 1272/2008 or Directive 67/548/EEC and Directive 1999/45/EC of the European Parliament and of the Council (8).

The evaluation of a product for hazards to the environment shall be performed by the conventional method as indicated in Annex III to Directive 1999/45/EC or by the summation method in Section 4.1.3.5.2 of Regulation (EC) No 1272/2008. However, as defined by Part C of Annex III to Directive 1999/45/EC or by Section 4.1.3.3 of Regulation (EC) No 1272/2008, the results of testing the preparation (either the product preparation or the additive package) as such can be used to modify the classification concerning the aquatic toxicity that would have been obtained using the conventional or summation method.

(b) Substances listed in accordance with Article 59(1) of Regulation (EC) No 1907/2006

No derogation from the exclusion in Article 6(6) of Regulation (EC) No 66/2010 may be given concerning substances identified as substances of very high concern and included in the list foreseen in Article 59 of Regulation (EC) No 1907/2006, when present in mixtures, in concentrations higher than 0,010 % (w/w).

Assessment and verification: the list of substances identified as substances of very high concern and included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 can be found here:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Reference to the list shall be made on the date of application.

Concentration limits shall be specified in the Safety Data Sheets according to Annex II, paragraph 3.2.1(c) of Commission Regulation (EU) No 453/2010 (9).

Criterion 2 – Exclusion of specific substances

The following stated substances are not allowed in quantities exceeding 0,010 % (w/w) of the final product:

- substances appearing in the Union List of priority substances in the field of water policy in Annex X to Directive 2000/60/EC of the European Parliament and of the Council (10) as amended by laid in Decision No 2455/2001/EC of the European Parliament and of the Council (11) and the OSPAR List of Chemicals for Priority Action (http://www.ospar.org/content/content.asp?menu=00950304450000_000000_000000),
- organic halogen compounds and nitrite compounds,
- metals or metallic compounds with the exception of sodium, potassium, magnesium and calcium. In the case of thickeners, also lithium and/or aluminium compounds may be used up to concentrations limited by the other criteria included in the Annex to this Decision.

Assessment and verification: conformance with these requirements shall be stated in writing and signed by the applicant.

Criterion 3 – Additional aquatic toxicity requirements

The applicant shall demonstrate compliance by meeting the requirements of either criterion 3.1 or criterion 3.2.

Criterion 3.1. – Requirements for the lubricant and its main components

Acute aquatic toxicity data of the main components and the mixture shall be provided.

Acute aquatic toxicity data for each main component shall be stated on each of the following two trophic levels: algae and daphnia (12). The critical concentration for the acute aquatic toxicity for each main component shall be at least 100 mg/L.

Acute aquatic toxicity data for the applied lubricant shall be stated on each of the following three trophic levels: algae, daphnia and fish. The critical concentration for the acute aquatic toxicity for a lubricant in Category 1 and 5 shall be at least 100 mg/L and for a lubricant in Category 2, 3 and 4 at least 1 000 mg/L.

Table 2 summarises the requirements for the different lubricant categories according to criterion 3.1.

Assessment and verification: either marine or freshwater toxicity data are accepted. The tests are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 or OECD 201 or Part C.3 of the Annex to Council Regulation (EC) No 440/2008 (13) for algae, ISO TC 147/SC5/WG2 or OECD 202 or Part C.2 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for fish. Equivalent test methods as agreed with a competent body are also permitted. Only (72hr)ErC50 for algae, (48hr)EC50 for daphnia and (96hr)LC50 for fish are accepted.

Criterion 3.2. – Requirements for each stated substance present above 0,10 % (w/w)

Chronic toxicity test results in the form of No Observed Effect Concentration (NOEC) data shall be stated on each of the following two aquatic trophic levels: daphnia and fish.

In case chronic toxicity test results are missing, acute aquatic toxicity tests results shall be provided for each of the following two trophic levels; algae and daphnia. One or more substances exhibiting a certain degree of aquatic toxicity are allowed in each of the five lubricant categories for a cumulative mass concentration as indicated in Table 1.

Assessment and verification: No Observed Effect Concentration (NOEC) data on the two trophic levels, daphnia and fish, are established by the following test methods: Part C.20 and Part C.14 of the Annex to Regulation (EC) No 440/2008 for daphnia and fish respectively, or equivalent test methods as agreed with a competent body.

Either marine or freshwater acute toxicity data are accepted on algae and daphnia. The tests in marine water are carried out according to and using relevant test species mentioned in the following guidelines: ISO/DIS 10253 or OECD 201 or Part C.3 of the Annex to Regulation (EC) No 440/2008 for algae, ISO TC 147/SC5/WG2 or OECD 202 or Part C.2 of the Annex to Regulation (EC) No 440/2008 for daphnia and OECD 203 or Part C.1 of the Annex to Regulation (EC) No 440/2008 for fish. Equivalent test methods as agreed with a competent body are also permitted. Only (72hr)ErC50 for algae and (48hr)EC50 for daphnia are accepted.

Assessment and verification for Criteria 3.1 and 3.2: high quality test reports or literature data (testing according to acceptable protocols and GLP) including the references shall be submitted to the competent body demonstrating compliance with the requirements set out for the aquatic toxicity in Table 1.

In the case of slightly soluble substances or preparations (< 10 mg/L) the method of the water-accommodated fraction (WAF) can be used in the aquatic toxicity determination. The established loading level, sometimes referred to as LL50 and related to the lethal loading, may be used directly in the classification criteria. The preparation of a water-accommodated fraction shall follow the recommendations set out according to one of the following guidelines: ECETOC Technical Report No 20 (1986), Annex III to OECD 1992 301 or the ISO Guidance document ISO 10634, or ASTM D6081-98 (Standard practice for Aquatic Toxicity Testing for Lubricants: Sample Preparation and Results Interpretation or equivalent methods). In addition, demonstration of the absence of toxicity for a substance at its limit of water solubility shall be deemed to have met the requirements of this criterion.

An aquatic toxicity study does not need to be conducted when:

- the classification of the substance, base fluid or additive is already stated on the Lubricant Substance Classification list, or
- a valid letter of compliance from a competent body can be submitted, or
- the substance is unlikely to cross biological membranes MM > 800 g/mol or molecular diameter > 1,5 nm (> 15 Å), or
- the substance is a polymer and its molecular weight fraction below 1 000 g/mol is less than 1 %, or
- the substance is highly insoluble in water (water solubility < 10 µg/l),

as such substances are not regarded as toxic for algae and daphnia in the aquatic system.

The water solubility of substances shall be determined where appropriate according to OECD 105 or equivalent test methods.

The molecular weight fraction below 1 000 g/mol of a polymer shall be determined according to Part A.19 of the Annex to Regulation (EC) No 440/2008 or equivalent test methods.

Criterion 4 – Biodegradability and bioaccumulative potential

Requirements for the biodegradability and bioaccumulative potential shall be fulfilled for each stated substance present above 0,10 % (w/w).

The lubricant shall not contain substances that are both: non-biodegradable and (potentially) bioaccumulative.

However, the lubricant may contain one or more substances with a certain degree of degradability and potential or actual bioaccumulation up to a cumulative mass concentration as indicated in Table 1.

Assessment and verification: conformity shall be demonstrated by providing the following information:

High quality test reports or literature data (testing according to acceptable protocols and GLP) including the references on the biodegradability and when required on the (potential) bioaccumulation of each constituent substance.

4.1. Biodegradation

A substance is considered ultimately biodegradable (aerobic) if:

1. In a 28-day biodegradation study according Part C.4 of the Annex to Regulation (EC) No 440/2008, OECD 306, OECD 310 the following levels of biodegradation are achieved:

   - in the ultimately biodegradable tests based upon dissolved organic carbon ≥ 70 %,
   - in the ultimately biodegradable tests based upon oxygen depletion or carbon dioxide generation ≥ 60 % of the theoretical maxima.

In these ultimately biodegradable tests the 10-day window principle will not necessarily apply. If the substance reaches the biodegradation pass level within 28 days but not within the 10-day time-window, a slower degradation rate is assumed.

2. The BOD5/ThOD or BOD5/COD ratio ≥ 0,5. The BOD5/(ThOD or COD) ratio can only be used if no data based on Part C.4 of the Annex to Regulation (EC) No 440/2008, OECD 306 or OECD 310 or any other equivalent test methods are available. The BOD5 shall be assessed according to Part C.5 of the Annex to Regulation (EC) No 440/2008 or equivalent methods while the COD shall be assessed according to Part C.6 of the Annex to Regulation (EC) No 440/2008 or equivalent methods.

A substance is considered inherently biodegradable if it shows:

- a biodegradation > 70 % in the Part C.9 of the Annex to Regulation (EC) No 440/2008 or OECD 302 C test for inherent biodegradation or equivalent methods, or
- a biodegradation > 20 % but < 60 % after 28 days in Part C.4 of the Annex to Regulation (EC) No 440/2008, OECD 306, OECD 310 tests based on oxygen depletion or carbon dioxide generation or equivalent methods.

The biodegradation test does not need to be conducted when:

- the classification of the substance, base fluid or additive is already stated on the Lubricant Substance Classification list or a valid letter of compliance from a competent body can be submitted,
- a substance is non-biodegradable if it fails the criteria for ultimate and inherent biodegradability.

The applicant may also use read-across data to estimate the biodegradability of a substance. 'Read-across' for the assessment of the biodegradability of a substance shall be acceptable if the reference substance differs by only one functional group or fragment from the substance applied in the product. If the reference substance is readily or inherently biodegradable and the functional group has a positive effect on the aerobic biodegradation then the applied substance may also be regarded as readily or inherently biodegradable. Functional groups or fragments with a positive effect on the biodegradation are: aliphatic and aromatic alcohol [-OH], aliphatic and aromatic acid [-C(=O)-OH], aldehyde [-CHO], Ester [-C(=O)-O-C], amide [-C(=O)–N or -C(=S)–N]. Adequate and reliable documentation of the study on the reference substance should be provided. In case of a comparison with a fragment, not included here above, adequate and reliable documentation of the studies should be provided on the positive effect of the functional group on the biodegradation of structurally similar substances.

4.2. Bioaccumulation

The (potential) bioaccumulation does not need to be established when the substance:

- has a MM > 800 g/mol, or
- has a molecular diameter > 1,5 nm (> 15 Å), or
- has an octanol-water partition coefficient, log Kow, value of < 3 or > 7, or
- has a measured BCF of ≤ 100 L/kg, or
- is a polymer and its molecular weight fraction below 1 000 g/mol is less than 1 %.

Since most substances used in lubricants are quite hydrophobic the BCF-value should be based on the lipid weight content and care must be shown to ensure a sufficient exposure time.

The bioconcentration factor (BCF) shall be assessed according to Part C.13 of the Annex to Regulation (EC) No 440/2008 or equivalent test methods.

The log octanol/water partition coefficient (log Kow) shall be assessed according to Part A.8 of the Annex to Regulation (EC) No 440/2008 or OECD 123 or equivalent test methods. In case of an organic substance other than a surfactant where no experimental value is available, a calculation method can be used. The following calculation methods are allowed: CLOGP, LOGKOW, (KOWWIN) and SPARC. Estimated log Kow values by any of these calculation methods < 3 or > 7 indicates that the substance is not expected to bioaccumulate.

Log Kow values are applicable to organic chemicals only. To assess the bioaccumulation potential of non-organic compounds, surfactants, and some organo-metallic compounds, BCF measurements shall be carried out.

Criterion 5 – Renewable raw materials

The formulated product shall have a carbon content derived from renewable raw materials that shall be:

- ≥ 50 % (m/m) for Category 1,
- ≥ 45 % (m/m) for Category 2,
- ≥ 70 % (m/m) for Category 3,
- ≥ 50 % (m/m) for Category 4,
- ≥ 50 % (m/m) for Category 5.

Carbon content derived from renewable raw material means the mass percentage of component A × [number of C-atoms in component A, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component A] plus mass percentage of component B × [number of C-atoms in component B, which are derived from (vegetable) oils or (animal) fats divided by the total

number of C-atoms in component B] plus the mass percentage of component C × [number of C-atoms in component C, which are derived from (vegetable) oils or (animal) fats divided by the total number of C-atoms in component C], and so on.

The applicant shall indicate on the application form the type (s), source(s) and origin of the renewable material(s) of the main components.

Assessment and verification: the applicant shall provide the competent body with a declaration of compliance with this criterion.

Criterion 6 – Minimum technical performance

a) For Hydraulic fluids: at least the technical performance criteria as laid down in the current ISO 15380, Tables 2 to 5. The supplier shall list on his product information sheet which 2 elastomers have been tested.

b) For Industrial and marine gear oils: at least the technical performance requirements as in the DIN 51517. The supplier shall list on his product information sheet which Section (I, II or III) was selected.

c) For chainsaw oils: at least the technical performance criteria as laid down in the RAL UZ 48 of the Blue Angel.

d) For two-stroke oils for marine applications: at least the technical performance criteria laid down in 'NMMA Certification for Two-Stroke Cycle Gasoline Engine Lubricants' of NMMA TC-W3.

e) For two-stroke oils for terrestrial applications: at least meet the EGD level of technical performance criteria laid down in ISO 13738:2000.

f) For all other lubricants: fit for purpose.

Assessment and verification: the applicant shall provide the competent body with a declaration of compliance with this criterion, together with related documentation.

Criterion 7 – Information appearing on the eco-label

Optional label with text box shall contain the following text:

- Reduced harm for water and soil during use
- Contain a large fraction of biobased material'.

The guidelines for the use of the optional label with text box can be found in the 'Guidelines for the use of the EU Ecolabel logo' on the website: http://ec.europa.eu/environment/ecolabel/promo/logos_en.htm

Assessment and verification: the applicant shall provide the competent body with a sample of the product packaging showing the label, together with a declaration of compliance with this criterion.

ANNEX I. TABLE OF COMMENTS

The following table consist on the comments received in the last written consultation after TR3.0 publication and relate to the third criteria proposal.

Scope and definitions

Comments	JRC Dir. B response
Revise definition for critical concentration for the aquatic toxicity to be in line with that for chronic aquatic toxicity: *means the concentration of a substance at and above which it will cause adverse effects to an aquatic organism following exposure to that substance*	**PARTIALLY ACCEPTED** The terms of 'Acute aquatic toxicity' and 'Chronic aquatic toxicity' have not been modified. They are in line with CLP regulation. The term 'Critical concentration for the aquatic toxicity' which is relevant for criterion 2.1 has been partially modified to reflect that this concentration could refer either to acute or to chronic toxicity.
Revise definition for acute aquatic toxicity to be in line with that for chronic aquatic toxicity: *means the intrinsic property of a substance to cause adverse effects to an aquatic organism...*	
When defining Ready biodegradation suggest clarifying that this relates to ultimate degradation. Also suggest that new criterion #3, 'other scientific evidence' should specify that it relates to ultimate degradation so there is no confusion with another type (e.g. primary): *Readily biodegradable means a substance that rapidly and ultimately degrades in the environment. 3. if other scientific evidence is available to demonstrate that the substance can be ultimately degraded…..*	**PARTIALLY ACCEPTED** **With regards readily biodegradable definition** Minor change in the definition has been introduced taking into consideration OECD definitions and CLP (chapter 4.1.2.9. Rapid degradability of organic substances): *'Readily biodegradable' means an arbitrary classification of chemicals which have passed certain specified screening tests for ultimate biodegradability; these tests are so stringent that it is assumed that such compounds will rapidly and completely biodegrade in aquatic environments under aerobic conditions. Substances are considered rapidly degradable in the environment if one of the following criteria holds true…:*
Concerning the readily biodegradable definition:...levels of biodegradation must be achieved within 10 days of the start of degradation which point is taken as the time when 10 % of the substance has been degraded, unless the substance is identified as an UVCB or as a complex, multi-constituent substance with structurally similar components. In this case, and where there is sufficient justification, the 10-day window condition may be waived and the pass level applied at 28 days. Based on our knowledge of the various base stocks offered by lubricant manufacturers for fluids that would be eligible for applying for the ecolabel we would caution the JRC/Commission that the 10-day is a very difficult criterion to meet for most non-aqueous, non-vegetable oil base stock, and could severely limit the ability of a lubricant manufacturer to formulate a product that has the relevant technical performance. *We suggest reverting to ultimately biodegradable and eliminating the 10-day window requirement for all substances and not just for UVCBs or complex multi-component substances.*	
Several industry stakeholders and associations:It is considered that the change in terminology used to describe the extent of degradation seen and the strict interpretation of this criterion including the 10-day window could significantly impair a lubricant manufacturer's ability to formulate fluids that have the necessary technical performance required by the market and still meets the revised ecolabel criteria. This is despite several concessions being made including the fact that the 10-day window would not apply to base stocks that could demonstrate that they qualified as UVCBs or complex, multi-component substances, and allowing products containing single component base stocks that show > 70% degradation, which does lessen	In the revised text, it is clearly reflected that biodegradation tests designed to determine whether an organic substance is 'readily biodegradable' is a way to demonstrate rapid degradation. In addition the criteria to be considered ***rapidly degradable*** (as

the impact of this criterion.	in CLP) are included in the definition (the wording was aligned in TR3.0).
Lubricants-Legal text Act. Article 2. Definitions (28). In the alternative 3." if other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level > 70 % within a 28-day period." *It should be clarified that, by the level > 70% is meant carbon dioxide generation and not dissolved organic carbon.*	**With regards the 10 days window** Considering the continuous opposition during the process from industry side and the uncertainty related to the impact on current licenses it is suggested to keep the possibility to waive the 10 day window for this revision. However, for future revisions it is proposed to explore in detail data on current licenses with this regards at an early stage of the revision, in order to know with certainty the impact of introducing the 10 day window in future revision. For this revision, it is therefore suggested to include the following text, in line with current text in force and Blue Angel. *'The 10 day window principle will not necessarily apply. If the substance reaches the biodegradation pass level within 28 days but not within the 10 day time-window a slower degradation rate is assumed'.* Any additional, more specific information regarding testing can be included in the User Manual.
We do not consider the inclusion of the 10-day window to be useful, as many base fluids are mixtures of chemically similar substances. In most cases evaluation of the 10-day window does not seem to be suitable for these mixtures. (OECD 2006. GUIDELINES FOR THE TESTRING OF CHEMICALS REVISED INTRODUCTION TO THE OECD GUIDELINES FOR TESTING OF CHEMICALS; SECTION 3 clause 43). Consequently terminology in that cases should use the term "biodegradability" instead of the wrong term "ready biodegradability". Moreover it should be noted that the designated tests on biodegradability do not have statements concerning the measurement uncertainty regarding substances, which are poorly soluble or are insoluble in water. This can cause false negative or false positive results with the corresponding risk of misleading the relevant user or stakeholder.	
We as a lubricant supplier do not know presently if the concessions being made (including the fact that the 10-day window would not apply to base stocks that could demonstrate being qualified as UVCBs) will be sufficient to allow the future use of the currently used readily biodegradable base stocks. A significant reduction of the number of approved base oils would jeopardise the beginning market success of EEL lubricants! *Think of the availability of adequate base oils in the market*	
Compared to the previous standard we see a change in the categorization. So far, a focus has been placed on use, so the new proposal is based on the classification according to the possible release. *In this classification we see especially for open gear oils and stern tube oils the applications as not classified correctly.* *1. The open gear oils should be classified as PLL. Example: Open gear drives usually have a collection container for collection the used oil or grease. The collected used lubricant will then be disposed professionally.* *2. Stern tube oils and greases are not TLL and therefore belong to ALL and PLL. Reason: stern tube as well as thruster is sealed with stern tube seals (lip seals or face seals). Lip type stern tube seals are also available as airspace seals. With airspace seals there is no leakage of oil into the sea (this would be category ALL). With normal stern tube seals (non-airspace type) there is a possibility for small operational losses of lubricant into the sea. However these losses are very small*	**PARTIALLY ACCEPTED** Stern tube oils and open gear oils have been places as PLL.

in comparison to the entire oil volume of a stern tube (this would be category PLL). Stern tube oils are changed during regular maintenance in dry dock and disposed professionally. Disposal in nature is strictly prohibited. *The case for categorizing stern tube oils as TTL is historic and flawed. Stern tubes are closed systems like hydraulic and gear. It is not possible in the market or the Ecolabel licensing system to segregate oils used in stern tubes from hydraulic or gear. Stern tube oils represent no greater environmental threat than these other applications and should be classified as ALL. (A case study has been provided)).*	
Although a specific definition is dedicated to the Letter of Compliance, there is no explanation or indication in the Decision on how a request for an LoC can be submitted and in which circumstances	**ACCEPTED** It is suggested to include information with this regards in the User Manual.
I still miss a separate, accidental loss category for greases. That would open up new opportunities, but I understand your point not to make it more complex. Although choosing any flowered product of course will be the better decision from environmental point of view, I am still unsure how the end-user will distinguish between general grease and total loss products, when they pick a "box from a shelf"	Criteria for have been differentiated within several sub requirements recognising the specificities associated to greases. Applicants would need to communicate to CBs the potential uses of the grease at application stage. To gain the label, a grease should comply with different thresholds considering its intended use. In relation consumers decisions, it is understood that a product is marketed indicating its intended use.
The new lubricant classification systems turn out to be problematic for greases. In addition it leads to illogical concentration ranges in Criterion 2 and 3. Also the link between the system and ISO 6743 is not convincingly since authors refer to a class that is MOSTLY covered by a specific ISO 6743 family therefore not in all cases. The new grouping method will lead to new discussions and debate in future revisions as was already the case at the last EUEB meeting on 06022018. *Several possibilities: 1) return to the specific lubricant classes; 2: remove the word mostly from the different lubricant families.*	**REJECTED** There is not a clear logic behind the existing values in force with regards the potential release/recovery of the different lubricant categories. The change in the structure aims to apply stricter values to TLL lubricants. It has been achieved in most of the requirements with the revised values, however some values remains as they are (or close) due to current licences. The revised values come from the merging of existing categories in force. The values have bene revised in order to keep a logical trend according to potential release. However exiting licences of lubricants (especially under category PLL did not allow to go for stricter values than ALL without losing licences). It is expected that the assessment of the licences in

	next revision considering the new categories would allow the refining of the values attending to its potential release.
The reasons to include MWF are not substantiated with relevant evidence in any of the technical reports. *Remove MWF from the class. It has not been shown in any report that the criteria can be applied to 15-20 of the market. Never has been given any description of the chemicals found in MWFs while this is easily available from scientific literature. In fact it has been mentioned several times that by far no MWF can qualify for the ecolabel. It has been stated that it may be important as ALL and for human health. While occupational (and not human) health might be a relevant issue there are no criteria referring to any occupational aspect. As ALL it can be inferred that MWF are used in factories only and not like motor oils or hydraulic fluids in areas where accidental loss is a likely issue. Potential release is unlikely at least compared to the ones that are currently included in the scope. The inclusion here is rather cosmetics than relevant or feasible.*	**REJECTED** One of the objectives in the current revision has been to expand the scope, so that more lubricant products find its way into the EEL. There are applications where a MWF can be formulated using biodegradable esters and additives to comply with the established limits. The MWF shall be dealt considering the marketed MWF, whether it is a neat oil, or an emulsion. Criteria have been set so that they can be applied to a neat oil as well to a water-containing product (i.e. the biodegradability criterion is applied to the organic part, that is C-skeleton). The EEL scheme is applied to the MWF products as they are sold. For instance, semi-synthetic MWF are emulsions, which are diluted in water during use, with dilution rates varying a lot depending on the type of mechanizing operation.

Assessment and verification

Comments	JRC Dir. B response
From several industry stakeholders and associations: Introduction of a statement that impurities are to be considered as intentionally added *We understand what the regulators are trying to do here and of course appreciate their recent concession on the no 'de minimis' limit for SVHCs, which now appears to be back to the amount indicated in the current standard. However, adding text that considers impurities to be intentionally-added (which of course they are not in the strictest sense) creates an additional practical anomaly. This is because in some cases applicants will be expected to generate/submit test data on impurities separate from the actual intentionally-added ingredients. The ingredients that additive manufacturers and lubricant formulators use necessarily contain low levels of impurities because we do not operate in a pharmaceutical-like manufacturing environment. Additionally, when test data is developed on those ingredients, the impurities are present and so generating data on the impurities themselves seems to be disproportionate. Some regulators may consider that REACH data should exist for raw materials used to make the ecolabel fluid ingredients (and which typically exist in the finished product as impurities) but they misunderstand that REACH data may not be available to formulators for non-REACH purposes without*	**PARTIALLY ACCEPTED** ECHA guidance for identification of substances under REACH and CLP defines "Impurity" as *"an unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added"*. The intention of this criterion is not to create need

them having to pay for access to the data again. A practical solution, that does not recue the level of protection provided by having robust test data, would be to waive aquatic toxicity and environmental fate data from applicants where they can provide the same data on an ingredient containing the impurity.	for additional testing, but to exclude potential higher presence of undesired classified known impurities in raw materials. The mentioned in the comments phrase regarding impurities is proposed to be modified as follows: *For the purpose of criterion 1impurities stated in the SDS, which presence in the final product equals or exceeds 0.01%, shall comply with the same requirement as the intentionally added substances.* This text has been included in criterion 1.
The definition of intentionally added substances contradicts the ECHA guidance for identification of substances under the REACH and CLP	
The reference of intentionally added substances is not supported. How should it be understood? If the manufacturer does not consider a substance "intentionally added" he would not have to declare it?	
The introduction of the statement that impurities are to be considered as intentionally added substances creates additional hurdle and requires additional testing for each impurity.	
The ingredients that additive manufacturers and lubricant formulators use necessarily contain low levels of impurities because we do not operate in a pharmaceutical-like manufacturing environment. Additionally, when test data is developed on those ingredients, the impurities are present and so generating data on the impurities themselves seems to be disproportionate. *A practical solution would be to waive the request for SDS information of impurities when the requested properties have been tested in the ingredient containing the impurities.* *Waive the request for SDS information of impurities when the requested properties have been tested in the ingredient containing the impurities.*	
For the purpose of this Decision, impurities stated in the SDS should be treated as intentionally added substances. *This means that impurities are accepted at the level of the classification limit, which is in line with the approach of the Blue Angel.*	
Assessment and Verification, 7th paragraph. Concerning the newly inserted condition that "For the purposes of this Decision, impurities stated in the SDS should be treated as intentionally added substances", this defintion is problematic for two reasons. Firstly, the manufacture of industrial substances typically does not produce substances with the purity expected in, for example, the pharmaceutical industry and secondly this defintion will create uncertainty for an applicant where other sections of the criteria document require testing of all intentionally-added substances (e.g. Criterion 2.2) since impurities are typically not isolated by the ingredient supplier/lubricant manufacturer. In fact, the REACH guidance for identification and naming of substances under REACH and CLP describes impurities as unintended constituents present in a substance, and which may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. The guidance is clear that while impurities are present in the final substance, they are not intentionally added. : *For the purpose of this Decision, impurities stated in the SDS should be treated as intentionally added substances <u>where their presence in the final product can be avoided by the applicant.</u>*	
*I have a comment or question on the **threshold limit of specified restricted substances (0.010%;** top of page 25 of TR 3.0): It is unclear to me if the expression "intentionally added" includes or excludes impurities potentially coming with the use of a UVCB substance (UVCBs are very frequent as lubricant additives) which has been REACH registered but not fully characterised in its compositition. A UVCB substance can contain other substances as part of the UVCB composition (e. g.*	

*starting material etc). It is sometimes very difficult to characterise all impurities down to a level of 0.01%. My interpretation would be that the formulator, when using the a. m. UVCB substance for his formulation, does **not intentionally** add a potentially present impurity if he (and the supplier) does not know about its existence. Is this correct or could you please clarify?*	
The sentence: "For the purpose of this Decision, impurities stated in the SDS should be treated as intentionally added substances". Could be misleading. It is our understanding that this is true only if the impurity would result in a final concentration in the Lubricant of or higher than 0,01%. *Proposal: Complete the sentence in the following way:* *"For the purpose of this Decision, impurities stated in the SDS should be treated as intentionally added substances when they result in a concentration of 0,01% or above in the final Lubricant.*	
The impact of introducing compliance for impurities and not only additionally added substances shall be considered.	
In relation to the statement: For the purpose of this Decision, impurities stated in the SDS should be treated as intentionally added substances *This means that any test report submitted for a REACH registration file on biodegradation and/or acute or chronic ecotoxicity to verify criterion 2 and 3mof the EEL is invalid.* *Impurities stated in the SDS must be treated as intentionally added substances only for criterion 1. Impurities stated in the SDS must be considered in criterion 2 and 3 if no test report has been submitted. (Thus when Read-Across, QSARs etc are used in the compliance assessment).* *It makes all test reports submitted within a REACH registration of the substance for compliance with criterion 2 and 3 invalid.*	**ACCEPTED** In the criterion 1 text has been included to clarify that the compliance for impurities is required only for the criterion 1. Therefore test data does not need to be provided/generated separately on impurities with regards to criterion 2 or 3.
(b) Measurement thresholds. The text: "In addition, the total fraction of the listed substances where the formulated criteria 2 and 3 do not apply shall remain below 0,5 % (w/w)." *needs clarification. It is difficult to understand what is meant by the text. Please use the text that is in the current criteria document. It is clearer (of course only if the meaning is the same).*	**REJECTED** The quoted in the comment text is the same as the text in the currently valid criteria, with the exception of the word "listed", which is used instead of "stated".
LoC should be also mentioned in the general assessment and verification text	**ACCEPTED**

Third proposed Criterion 1: Excluded and limited substances

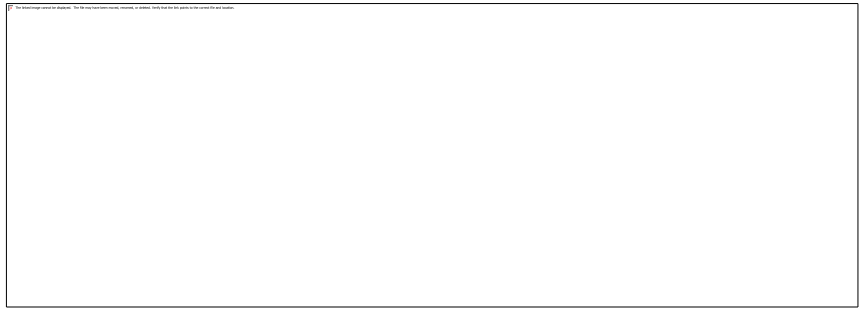
Comments	**JRC Dir. B response**

You say that you are trying to harmonise the lubricants ecolabel with the detergents ecolabel, but the detergents criteria don't include restrictions on substances with the following classifications: • *H335 May cause respiratory irritation* • *H336 May cause drowsiness or dizziness* • *H315 Causes skin irritation* • *H318 Causes serious eye damage* • *H319 Causes serious eye irritation* • *EUH029 Contact with water liberates toxic gas* • *EUH031 Contact with acids liberates toxic gas* • *EUH032 Contact with acids liberates very toxic gas* • *EUH066 Repeated exposure may cause skin dryness or cracking* *Please can you remove these restrictions from the lubricants EU ecolabel restrictions as it is impossible to produce a lubricating grease, that is soap based and inherently irritating due to their surfactant and detergent properties.*	**CLARIFICATION** The criteria is partially harmonized with detergents and other EU Ecolabel. However there are differences that are specific for this product group. The statements **included in existing Commission Decision for Lubricants** have been kept in order to not decrease the ambition level in this revision. However due to the potential drop of licences expected if the EU Ecolabel horizontal approach (0.01% threshold per classified substance; applied already in detergents and many other EU Ecolabel product groups) is followed, for lubricants, a more flexible approach have been agreed along the consultation process (partially aligned to the Blue Angel one). For majority of hazard statements listed in the corresponding comment, the proposed threshold is **Final product classification**. This is **existing limit in force**. Therefore, no impact is expected on licences presenting those hazards. Only for H335, EUH029, EUH031, EUH032 (from the statements mentioned), the horizontal value of 0.01% per substance present in the final product applies. This is based on the assessment made on current licences and LuSC list substances, which revealed the possibility to apply the EU Ecolabel horizontal approach with no potential impact on current licences. See more information about this assessment in the rationale of TR3.0. In case the application of the 0.01% threshold to H335, EUH029, EUH031, EUH032 statements is problematic for a number of licences additional evidence should be provided by the stakeholders to include it in the assessment.
Why additional Hazard statements have been added to the usual horizontally used in other product groups?	

What would be the process for ecolabel products that have component hazard label changes occurring due to Reach registrations. For example, if a component part of a lubricant, when registered for the ecolabel was associated with no hazard, but later the hazard changed to a restricted hazard statement or statements. What would be the notification process? Could a temporary Ecolabel template be issued to allow time for appropriate full product testing to be carried out, similar to the OSPAR process.	**CLARIFIED** This is an issue which is currently discussed internally within the framework of the Hazardous Task Force 2. As a result of this work guidance will be developed on how to proceed in the mentioned situation to ensure harmonised treatment of licences across all CBs. Specific explanation for the applicants will be then available at the DG ENV website and in the User Manual.
There seems to be quite a few soap type substances that are now being reclassified as eye irritant (H319) or skin irritant (H315) for reach registrations. If all soap structures end up with these warnings would there be any scope to allow certain hazard statements, or appropriate limits on certain hazard statements to be allowable for the lubricant ecolabel classification? As is the case with the detergents Ecolabel which has many allowable hazards.	
A general exemption of Annex IV and V substances is not justified. Annex IV for example contains EC 267-013-3 fatty acids C6-12 that are classified and would on their own trigger a SDS according to chapter IV of REACH from which they are not exempted. The same could apply to natural substances that are not chemically modified as indicated in Annex V No. 7 (which for example covers minerals and ores that might carry hazardous properties).	**CLARIFIED** This is a horizontal requirement, which applies only to substances exempted from registration obligations under Article 2(7)(a) and (b) of REACH.
From several industry stakeholders and associations: *a) Setting a limit on the content of skin sensitising ingredients in the finished fluid that is 50% lower than that allowed by Blue Angel (RAL UZ-178)* *According to previous comments made by JRC the limits set in Table 1 are based on a hazard grouping defined by the EU Ecolabels Chemical Horizontal Task Force. As such JRC appears to consider sensitisers to be a Group 1 substance (i.e. subject to complete restriction in ecolabel products), which places them in the same grouping as CMRs, PBTs/vPvBs and endocrine disruptors. Confusingly 'allergens' are also indicated in the 3rd Technical Report as being in Group 2 and JRCs response to comments made after the 2nd Technical Report suggests that they still consider skin sensitisers to be a member of the 'priority concern' group (either 1 or 2). Recently, however, at least one competent body (ANSES) has produced a paper confirming that skin sensitisers do not meet the REACH Article 57(f) 'equivalent concern' criteria and so we request that the limit for skin sensitisers in the finished product should be harmonised with that found in the Blue Angel and should be changed from less than 0.5 x final product classification limit for H317 to less than the classification limit for H317 (i.e. < 0.1% for Category 1 and Category 1B sensitisers and < 0.1% for Category 1A sensitisers).*	**CLARIFIED** The prioritisation used in the EU Ecolabel criteria is not the same as the prioritisation of REACH. It is a result of discussions and agreement reached in the framework of the 1st Hazardous Task Force, concluded in 2014. It is though true that this specific hazard is of lower concern with regards to this specific product group, than for instance for the detergents product group. Following the feedback the threshold will be set in alignment with the Blue Angel requirement (i.e. final product classification).
Limit value for skin sensitiser is set at 0.5 x Final product classification limit for H317. Sensitisers are no longer considered to be substances of equivalent concern according to documents published by at least one competent authority (ANSES?) and so we suggest that the limit value for these substances should be brought mopre into line with Group 3 substances described in the EU ecolabel Horizontal Task Force report. This would also bring the EU ecolabel into agreement with the limit for skin sensitisers found in the updated Blue Angel (RAL UZ-178) - See Table 3.3 on page 32 : *Limit value for skin sensitiser is < Final product classification limit for H317*	

H317 *There are two different concentrations for classifying a product with H317: If the ingredient is a skin sensitiser 1A, the classification limit is* *>=0,1%, if the ingredient is a skin sensitizer 1 or 1B the liemit is >= 1 %.* *As a result, two different criteria apply to the product. For category 1A sensitizing substances, a maximum value of 0.05% applies, for* *substances of category 1 or 1B a maximum value of 0.5% applies.* *This criterion should be clarified.* *Moreover, the vague possibility of skin sensitization should not be viewed with that great concern (0.5 of classification limit). A maximum value analogous to the criteria for the Blue Angel should fully guarantee the protection of the users and the launch of the ECO label.*	
H317: ECHA is studying the possibility to label H317 the MIT biocide for c> 15 ppm (now 1000 ppm). This would impact aqueous mold release agents if this new limit becomes applicable.	
H317 is quite relevant for lubricants but since lubricants refer to lost lubricants into the environment the relevance for potential consumer exposure from the product is extremely low. *H317: to final product classification limit for H317* *The Chem HTF approach paper indicates clearly on page 25 number 2.8 that Hazard classes H317 and H334 shall be added to the list WHERE THEY ARE RELEVANT TO POTENTIAL CONSUMER EXPOSURE FROM THE PRODUCT. This is clearly not the case for lubricants and since it is a more critical one there is no reason to derogate to below the classification limit. It would also make this limit value in line with the Blue Angel.*	
Aspiration hazard limit is set at 0.5 x classification limit for Asp Tox 1 (i.e. 10%). However, classification of a product for Aspiration hazard is dependent on two criteria - wt% of ingredeints with Asp Tox 1 hazard AND the kv40 of the finished product. Additionally, most synthetic base stocks with a viscosity of <20.5 cSt will be hydrocarbons and will therefore be classified as Asp Tox 1 hazard. Limiting the amount of Asp Tox 1 ingredients to ≤ 5% could contradict the intent of the new raw material criterion in opening up the possibiity of other synthetic base stocks being accessible to lubricant formulators.: *Product should not be classified as aspiration hazard*	**CLARIFIED** The proposed requirement is aligned with the Blue Angel approach regarding the threshold, as agreed along the criteria revision process. It is required that Substances *that would lead to classification in the hazard class "Aspiration Hazard" may only be contained in the final product up to a maximum of half of the relevant concentration that would lead to classification of the final product in the hazard class "Aspiration Hazard" in accordance with the guidelines in Regulation (EC) No 1272/2008 for the final product.* According to CLP, where the aspiration toxicity of a mixture is based on its components, two conditions need to be met. First, a mixture must contain a total of
H304 *There is no apparent reason why the aspiration toxicity limit is lowered so much. Danger from low-viscosity hydrocarbons usually only occurs when they are inhaled directly or aspirated after ingestion and vomiting. This is directly related to the viscosity of the inhaled or swallowed product, in this case the finished lubricant.* *The aspiration toxicity of constituents is therefore never a criterion for finished products with a viscosity of> 20.5 cSt, to which a risk to users*	

or the environment can be attributed.	10% or more of a substance or substances classified in Aspiration Toxicity category 1. Secondly, the kinematic viscosity of the mixture must be at or below 20.5 mm2/s, measured at 40°C (section 3.10.3.3.1.1 of Annex I to CLP). When these conditions are both met, the mixture must be classified in Aspiration Toxicity Category 1. **With regards to the newly proposed criterion the concentration allowed is not 10% but it is lowered to 5%. The requirement 1(a) (ii) on substances set limit ONLY for concentration in the final product.** In Criterion 1(a)(i) is required that the final product should not be classified with Aspiration hazard. .
H304: Mineral and/or synthetic oils are labeled H304 if their viscosity is <20.5 mm2 / s @ 40 ° C.	
As the classification limit for H304 is >= 10% content and final viscosity <= 20,5% the "limit value" in table 1 is not sufficient to cause a classification as H304. Thus >= 10% H304 ingedrients would not cause H304 labelling if the viscosity of the final product is >20,5 mm²/s. From that point of view it is not clear if there is a limit of max. 10% H304 ingredients or not!? *Clarifying of limit value*	
Setting a limit for skin hazard (EUH066) and acute toxicity (H301, H311 and H331) *There is currently no General Concentration Limit for classifying mixtures containing substances that are assigned the EUH066 supplemental hazard statement. CLP Regulation 1272/2008 refers to "practical observations or relevant evidence concerning their predicted effects on the skin", and both hazard criteria are at least semi-qualitative in nature and are not easily verifiable by competent bodies. VSI members suggest that this hazard statement should be omitted from Table 1, or that the limit should be set to an arbitrary level (e.g. <20%) that is greater than the GCL for substances classified as a skin irritant (H315).* *Similarly, since the implementation of CLP mixtures are no longer classified for acute hazard based on the percentage content of acutely toxic substances. Instead an acute toxic estimate (ATE) is calculated based on the contribution of all ingredients and this then determines the classification of the product in terms of acute toxicity. This means that there is no percentage regulatory threshold for classifying mixtures and the final product classification for acute hazard also depends on the other substances present and whether data exists for them or not. We would suggest that the criteria in Table 1 should be that the final product should not be classified as H301, H311 or H313 rather than specifying a fraction of a limit that no longer exists.*	**CLARIFIED** With regards to the classification with EUH066 the CBs would be required to check the product SDS to verify if the product is classified with this hazard. Regarding the classification with H304 as explained above the proposed limit is aligned with the Blue Angel criteria, as agreed in the revision process. For H301, H311 or H313 the limit proposed is < final product classification.
Limit for substances that are classified as acute toxicity 4 (oral, dermal and inhalation toxicity) is set at the threshold at which classification of mixtures would occur as Acute Tox 4. Since the implementation of CLP this is no longer how the finished product acute toxicity classification is calculated. Instead an acute toxic estimate (ATE) is calculated based on the contribution of all ingredients and this then determines the classification of the product in terms of acute toxicity. This means that there is no % threshold set for the product classification limit and the final product classification in these hazard classes/catgeories will also depend on the other substances present and whether data exists for them or not. An	

alternative is therefore needed to < final product classification limit for H301/311/331 : *Product should not be classified as acute toxicity by oral, dermal or inhalation routes*	
After two rounds where more than 90% of the licenses would have been lost, it is still difficult to assess within a certain range the impact on the current licenses. In addition despite the enlargement of the scope it is anticipated that ony new licenses within the current categories will be requested. *State the estimated fraction of licenses lost based on information received.* *It is quite difficult to assess the impact but given that it is the 3rd round but the first where only a fraction is lost there is ample time to check if the impact is still large or acceptable. And then what is acceptable? And if 10% is lost on the LuSC-list but these ones are used more frequent the impact on the lubricant licenses is larger. The Blue Angel limit value is not 0% but 0.010% as can be seen on page 18 from their criteria document (178-1407)* *Improve the table* *Now it looks like as if the Blue Angel does not accept any of these substances irrespective of their concentration. That is not the case.*	**PARTIALLY ACCEPTED** Detailed analysis of the predicted impact of the revised criterion 1 on current licences (based on the data provided to the project team) can be found in chapter 3.1. For certain hazard classifications, where according to the information provided, difficulties to comply with the strict interpretation of the hazardous substances criterion are expected to be encountered, a more flexible approach was proposed. Thus the horizontal approach is not applied fully. Specificities of the substances used in lubricant products (for which data was provided by the industry) are taken into account. Indeed the Blue Angel refers to all substances, added and/or created, including impurities, present above 0.01 % w/w in the final product. Respective clarification was introduced in the report.
Thank you for taking into consideration the information provided within the Safety Data Sheets (SDS) of all our products listed on the LuSC list. It should be considered again, that the main changes within the criterion 1 still imply the risk of the potential loss of current licenses, if the proposed criterion is implemented. *I specifically refer to the assessment made regarding the Part II of the LuSc list.*  *This assessment is taking into consideration base stock fluids, which by nature rarely carry H phrases, compared to additives.* ***The evaluation should be broken down and assessment (i.e. impact analysis) made separately for Base fluids, Thickeners, Additives and Polymer systems.*** ***If we lose 10-15% of licenses in total, mainly additives will be affected****. Additives are the core of finished lubricant, as they are enabling the necessary technical performance. Even if the license for additives is not entirely lost,* ***if the additive treat rate is severely reduced****, then it is not feasible to produce lubricant which is giving required technical performance. The*	

final treat rate is a combination of many factors, especially if we talk about UVCB substances and small fractions. *There will be no reason for formulators to apply for EU Ecolabel at the end if the treat rate of products listed on the LuSc list does not enable formulation of finished lubricant. The effect on the current licenses, but also on EU Ecolabel would be larger than currently perceived.* *The addition of statement* ***that impurities are to be considered as intentionally added substances****, only worsens the situation.*	
a) Omission of the current derogation for excluded or limited substances based on the overall product classification *UEIL HSE members continue to highlight the risk of the potential loss of current licenses if the Criterion 1 is implemented as proposed in the Technical Report 3.0. We specifically refer to the impact assessment made regarding Part II of the LuSC list where approximately 30% of the currently approved products would be adversely affected by this change, and which would effectively be disqualified from use in an ecolabel lubricant because their treat rate would be significantly reduced. We believe that the assessment seriously under-estimates the impact on current LuSC listed substance/products, and therefore on the ability of formulators to develop a lubricant. This is because the impact assessment on Part II of the LuSC list includes a high proportion of base stock fluids, which by their nature rarely carry any Hazard phrases compared to other ingredients such as thickeners, performance additives and polymer systems. We therefore request that the impact assessment should be repeated separately for base stock fluids and 'other additives', to illustrate the true potential impact on these 'other additives'. We believe that this is necessary because these 'other additives' are critical parts of a finished lubricant, enabling it to meet the necessary technical performance. Even if the hazard profile of LuSC listed additives does not automatically disqualify them from being used, the proposed Criterion may result in the treat rate being reduced to a level where it is not possible to produce a lubricant giving the required technical performance*	
Does it mean that a final product can contain raw material with H400 substances above 0,01% if the final product is not classified hazardous to the environment ?	**CLARIFIED** Yes, the product can contain H400 classified substances up to sum-total of 0.5 the concentration, which would lead to the final product classification limit for H400. See approach followed explained in chapter 3.1.
Several typos in assessment and verification section: SDS instead of MSDS *Spacing for intentionally added.*	**REJECTED** ECHA guidance refers to safety data sheets for both, substances and mixtures.
Suggest alternative text for last two sentences:	**ACCEPTED**

In addition, a declaration from the applicant and their suppliers should be provided for requirement 1c, if appropriate. The above evidence can also be provided to Competent Bodies by any supplier in the applicant's supply chain.	Modified.
Table 3.6. The explanation given for the limit values referring to the hazard category (column 4, Blue Angel Limit Value) is more understandable than the proposed limit referring to the classification limit final product (column 3, Proposal Limit)	**REJECTED** Chapter 3.1 explains in detail the approach followed to obtain the values proposed in column 3.
Table 3.6. Proposed limit. Stick to using either 'Classification limit final product' or 'Classification limit (final product)' for consistency	**ACCEPTED** Modified.
Table 3.6. Note [3] for aspiration hazard is missing?	Comment unclear
In order to avoid confusion in the interpretation of the sentence we suggest a minor editorial change, by moving "the final product" soon after the expression "shall not be intentionally added or formed" *The sentence could be :* *Substances that meet the criteria for classification as acutely toxic, hazardous to the aquatic environment, respiratory or skin sensitiser, carcinogenic, mutagenic or toxic for reproduction in accordance with Annex I to Regulation (EC) No 1272/2008 shall not be intentionally added or formed in the final product at or above the concentration specified in Table 1 for each hazard statement.*	**ACCEPTED** Modified
Typo mistake in the table, in the line settling the limit concentration in case of substances with H410, H411, H412 and H413: *The sentence is "< Final product classification limit for H412 and H431" instead of "< Final product classification limit for H412 and H413". The sentence could be: "< Final product classification limit for H412 and H413"*	**ACCEPTED** Modified
Assessment and verification: *To demonstrate compliance with 1 (a) (i) the applicant shall provide the MSDS of the final product.* *To demonstrate compliance with 1 (a) (ii), 1 (b) and 1(c) the applicant shall provide:* • *SDS of intentionally added mixtures and their concentration in the final product.* • *SDS of intentionally added substances and their concentration in the final product.* *It is not enough to demonstrate the compliance with 1(a)(ii), 1 (b) 1(c) with a SDS because according to REACH rules a SDS only needs to show the classified substances included in concentrations > 1% and the SVHC substances included in concentrations > 0.1%. Therefore, declarations are needed as verification, as well.* *Please be consistent when you use the shortening for safety data sheet, SDS or MSDS.* *The inclusion of ban on classification of substances for aspiration hazard does not make sense. The final product testing needs to be conducted [to double check with Bernd]*	**CLARIFIED** **The first statement in the assessment and verification states that:** *The applicant shall provide a signed declaration of compliance with above sub-requirements, supported by declarations from suppliers, if appropriate***;** in addition to the safety data sheets. ECHA guidance refers to safety data sheets for both, substances and mixtures. Text has been modified accordingly.
It is good and clear and in line with own document from the CHTF dated 24022014 to set a starting level of 0.010%. It removes a lot of problems and discussions. *Absolute absence of a substance means not even one molecule is allowed. This is impossible to verify.*	**ACCEPTED**
What is the scientific reason to reduce the H304 (May be fatal if swallowed and enters airways) and H317 (May cause	Please see chapter 3.1 for explanation on how

allergic skin reaction) to half of the lowest classification limit, rather than the classification limit only?	threshold limits were set.

Third proposed Criterion 2: Additional aquatic toxicity

Comments	JRC Dir. B response
Proposal to add also algae (same methods but endpoint NOEC for chronic toxicity): ISO 10253 or ISO 8692 or OECD Test Guideline 201 or Part C.3 of the Annex to Council Regulation (EC) No 440/2008 for algae. *The logic behind this testing strategy is not fully understood. For the acute tests only daphnia and algae are required for the main components, but fish data are demanded for the lubricant. Further on for chronic toxicity the fish animal tests are considered. The algae assay OECD 201 is both being considered as an acute test (EC50) and as a chronic test (NOEC). Proposal: Suggestion to limit fish toxicity requirements or to shift to the non-animal FET test. Fish data should only be demanded when these have been submitted under other regulatory schemes (REACH). This will also be considered in the Blue Angel RAL-UZ 178.* ➔ *PARTIALLY ACCEPTED The aquatic plant growth inhibition tests (ErC 50) are normally considered as chronic tests but the EC 50 s are treated as acute values for classification purposes. fish embryo toxicity (FET) has been included when fish acute aquatic toxicity data need to be generated for acute aquatic toxicity data.* *Only NOEC or ErC10 are considered as chronic test result. Chronic toxicity is related to waterborne exposure and refers to the potential or actual properties of a substance to cause adverse effects to aquatic organisms during exposures which are determined in relation to the life-cycle of the organism. Such chronic effects usually include a range of sublethal endpoints and are generally expressed in terms of NOEC (No Observed Effect Concentration), LOEC (Lowest Observed Effect Concentration) or ECx (see ECHA Guidance R.7b version 4.0, June 2017). In this context ECx is EC10 or EC20 but not EC50.*	The trophic levels included are those existing in force. In previous revisions were selected as were considered the two most sensitive trophic levels for aquatic toxicity. However, during this revision it was find out that different organisms have different sensitivity to the toxics, it should be necessary to evaluate the most appropriate organism in order to establish the maximum permissible concentrations in aquatic ecosystems (lowest toxic value). Against this background, it was initially proposed in the TR1.0 that the aquatic toxicity test results were provided for all the three trophic levels and then selects the lowest toxic value based on the more sensitive organism. Nevertheless this proposal was rejected as this would increase the testing and majority of stakeholders opposed to the initial proposal. In the second draft and according to the stakeholder´s comments it was proposed to request data for the **same trophic levels according to REACH for the registration of substances and as in the current EU Ecolabel.** Main difference compare to the text in force is the introduction of possible use of other available data on chronic toxicity test in the absence of acute data: for daphnia and fish in main components and for the 3 trophic levels for lubricant. With regards your proposal on fish testing. For all the cases where fish data has to be generated the fish embryo toxicity (FET) is proposed. In relation to your following proposal*: Proposal to add also algae (same methods but endpoint NOEC for chronic*

	toxicity): ISO 10253 or ISO 8692 or OECD Test Guideline 201 or Part C.3 of the Annex to Council Regulation (EC) No 440/2008 for algae. → *ACCEPTED.* In addition, several wording amendments have been introduced in order to clarify further the potential data missing situations and how to fill data gaps.
The possibility of using QSAR data to fill data gaps for one trophic level only has been added to criteria 2.1 and 2.2: *It is suggested that suitable QSAR models for environmental data should be stated in criterion 2 or QSAR should be defined in section 1.2.1. The technical report 3.0 states that documentation on the validity and applicability domain of the applied model must be provided by the applicant). However, many applicants might not have the toxicology background to enable them to provide this information or judge what is a suitable SQAR model and what is unsuitable. More guidance should be provided in the User Manual by JRC.*	**PARTIALLY ACCEPTED** QSARs possibility has been deleted for lubricants when unknown substances are present in the mixture (final product-lubricant) (in this case up to 5% by weight in the lubricant). QSARs cannot be used to generate data for the lubricant (final product). .
QSAR can fill data gaps for only one trophic level. Are we sure that QSAR can be applied to the lubricant which can be a complex mixture?	It is suggested keeping this possibility for substances and main component. It is not of mandatory use so it would not suppose a burden on applicants who decide not using it. For those applicants, who decide to use QSARs to fill data gaps, validity and applicability domain of QSARs have to be provided to ensure reliability. We think that as a first step should be included in this revision. In the future, in the light of the results of these changes in the revised text, it should be discussed if the data gaps should be mandatorily fulfilled with QSARs.
Since for aquatic toxicity the two most sensitive trophic levels have been selected as in the current criteria instead of three and since in the current criteria no reference is made to the use of QSARs, its introduction at this proposal will most likely add more discussion and confusion. *Remove the verification by QSARs.* *It is not known and not mentioned in the technical report is a problem in the verification on this criterion is encountered. The available data must be checked to verify this criterion.*	
The major issue with QSARs is the uncertainty of the estimated value. QSARs may easily lead to an uncertainty of the estimated value that is larger than the value itself. *Add: the 95% prediction interval of the value may not be larger than the value itself. (Since in the current criteria no reference is made and is necessary to QSARs alternatively it can be removed from the text.)* *Uncertainty in the estimated value needs to be addressed. That is the reason why the validity and applicability domain are introduced. It is to have the lowest uncertainty in the estimated value if the estimated value is within the applicability domain.*	
Typo 1st line: *In case acute aquatic toxicity data for the applied lubricant is missing...*	**ACCEPTED**
Typo 1st line: *ISO 6341 or OECD test Guideline 202*	
Criterion 2.2 now specifies that data is required for each intentionally-added or intentionally-formed substance at or above 0.10% in the final product. Intentionally-added substances includes impurities as per section 2. However, test	**PARTIALLY ACCEPTED** In the general assessment and verification text it has been

data is usually generated on ingredients that contain low levels of impurities and so it would be disproportionate to expect applicants to generate aquatic toxicity data on impurities. Substances present in the product as an impurity will be specified in compositional disclosure (as function), and so it should be clarified (e.g. in the User Manual) that for the purposes of criterion 2 test data does not need to be generated separately for any impurity present in ingredients for which test data has been generated : *For the purposes of criterion 2 test data does not need to be generated separately for any impurity present in ingredients for which test data has been generated*	specified following: *For the purpose of criterion 1, impurities stated in the SDS should be treated as intentionally added substances* Therefore the statement only applies to criterion 1, thus test data does not need to be provided/generated separately on impurities.
The paragraph dealing with Available acute aquatic toxicity data for each main component is not very clear in terms on how to compensate the lack of the acute aquatic toxicity data. ***Available acute aquatic toxicity data for each main component** shall be provided on each of the following two trophic levels:* *- crustacean (daphnia preferred),* *- aquatic plants (algae preferred).* *In case acute aquatic toxicity data for each main component is missing (clarify if the data is missing for both trophic levels or for one), available data on chronic aquatic toxicity shall be accepted for each of the following two trophic levels (does it mean that both must be provided or just one could be accepted?):* *- crustacean (daphnia preferred)* *- fish.* *QSARs shall be accepted to fill data gaps in only one of the trophic levels. (clarify if this sentence refers only to chronic data or acute toxicity data or both)* *In case any of the above datafor each main component is not available, test will need to be performed to generate data on acute aquatic toxicity for each of the above mentioned specific trophic levels (i.e. crustacean and aquatic plants).:* *The sentence could be :* ***Available acute aquatic toxicity data for each main component** shall be provided on each of the following two trophic levels:* *- crustacean (daphnia preferred),* *- aquatic plants (algae preferred).* *In case one of the acute aquatic toxicity data for each main component is missing, available data on chronic aquatic toxicity for both of the following two trophic levels shall be accepted:* *- crustacean (daphnia preferred)* *- fish.*	**ACCEPTED** The text has been clarified.

QSARs shall be accepted to fill data gaps for chronic toxicity or for acute toxicity in only one of the trophic levels as referred above. *In case any of the above data for each main component are not available, test will need to be performed to generate data on acute aquatic toxicity for each of the above mentioned specific trophic levels (i.e. crustacean and aquatic plants).*	
In the sentence after the table: *"Available chronic aquatic toxicity data for each relevant substance shall be provided for each of the following two trophic levels:"* *It could be preferable to avoid misunderstanding to clarify that the involved substances are those at or above 0,1% and below 5%, that is to say that they are not the main components, which are regulated in a different way in the previous chapter.* *The sentence could be :* *"Available chronic aquatic toxicity data for each intentionally added or formed substance at or above 0,1 % (and below 5%)shall be provided for each of the following two trophic levels:"* *As in chapter 2.1 the sentence on QSAR is not clear enough* *The sentence could be:* *QSARs shall be accepted to fill data gaps for chronic toxicity or for acute toxicity in only one of the trophic levels as referred above.*	**REJECTED** The option 2.2 applies to all substances above 0,1 % with no limit in upper concentration. Applicant can choose among 2.1 (data on all main components (substances above 5%) +applied lubricants) or 2.2 (data on all substances above 0.1%).
The sentence : *"For each substance or main component where the assessment is based on the Lubricant Substance Classification list (LuSC-list) no documents need to be submitted."* *dealing with the use of LUSC data, could be better rephrased* *The sentence could be :* *For each substance or main component selected from Lubricant Substance Classification list (LuSC-list) the assessment can be based on the information reported in said List and no tests and data as per the herein criterion needs to be submitted.*	**PARTIALLY ACCEPTED**
The aquatic toxicity requirements of total loss greases are too strict. You left only a 2% window for harmful substances. I sent you before comments on lithium and lithium complex soaps, because they are classified in the LuSC list as harmful and it will be impossible to make TLL products with these soaps. The grease market is very conservative and lithium based products take the 80% of that. In the investigation that you reported in this 3rd technical document, you showed that this will only have a marginal effect on the current approved products. However, as those are non lithium products listed today, this is not a fair analysis and one cannot conclude that it does not close	**ACCEPTED** Values have been modified for greases.

out Li and LiX from TLL category. The point still remains… The only non-toxic soaps will be the calcium ones on the LuSC list. Lithium ones are harmful and aluminum complex is not classified. We can develop only calcium products for these applications in the future with all the limitations of this technology. *The 15% limit still close out the most developed technologies, for example LiX soaps. I understand, if you would like to decrease it gradually, but then let the high end products enter the market for accidental loss. So if you change the ALL harmful limit for grease to 20% or higher (25% was the original), we could live with that.* *In this case systems designed for partial or total loss are going to ban the harmful soaps, but we still can use them in closed bearings.* *I have another suggestion. You don`t need to increase the toxic level from 1% to 2,5% in case of ALL greases. That is the real "enemy". We should develop without toxic ingredients.*	
Why do we have two overlapping restrictions on substances classified as toxic to aquatic environment (i.e. through criterion 1 and 2)?	The criterion 1 has been revised. The limit for substances presenting H400 classification is half of the concentration leading to the product classification for H400. According to table 4.1.1 of CLP, the maximum concentration would be 25/M %. Thus, it depends on the M-factor, but if the M-factor is 1, the maximum concentration would be 25%. Then 12.5% would be allowed according to the EU Ecolabel. For chronic toxicity statements, H410, H411, H412 and H413 criterion 1 (a) (ii) refers to the maximum limit of total concentration leading to product classification for H412 and H413. CLP additivity for final product classification is considered, therefore the total concentration of substances presenting the chronic toxicity categories 1 to 4 is considered for the products classification. Criterion 2.2 goes beyond criterion 1, as a safety net for aquatic toxicity (additional aquatic toxicity), limiting the maximum mass concentration of the substances exhibiting the specific hazard statement **individually** (CLP additivity for final product classification is not considered in this case). For instance, the maximum cumulative mass concentration of substances classified as H400 or H410 allowed is ≤0,1/M % (w/w in the final product). If M=1, a

	0,1% cumulative mass will be allowed.
Typo MM800 g/mol	**ACCEPTED**

Third proposed Criterion 3: Biodegradability and bioaccumulative potential

Comments	**JRC Dir. B response**
We are pleased that grease has been classified separately as due to the semi solid, soap formed, sponge like structure, we believe that this is the correct classification as grease is quite a bit different to lubricating oils and should be treated differently. The one problem I can see is that the non-biodegradable and non-bioaccumulative limit for greases has dropped significantly from 25% in the current Ecolabel guidelines to 10% in this proposed edit (TR 3.0). Due to the semi solid nature of grease and the need for soap thickening which is classified as non-biodegradable and non-bioaccumulative and tends to account for around 15% of the grease. This non-biodegradable and non-bioaccumulative limit need to be at least 15%, ideally 20% would be better. Putting this limit at 10% would hugely hinder the production of ecolabel greases and most likely lead to a degradation in grease quality leading to low customer confidence on ecolabel grease performance.	**ACCEPTED** 11 out of 24 greases currently in EU Ecolabel would comply with the biodegradation criteria included in TR3.0 for TLL greases. No extra data about distribution of greases depending on the environmental release has been received. In the light of the comments received and considering that it is reasonable to conclude that a high percentage of the EU Ecolabel certified greases are TLL applications which are going to be used in sensitive areas, it is therefore suggested to further relax the values for TLL greases.
Several industry stakeholders and associations *Cumulative amounts of biodegradable, partially degradable and non-degradable substances allowed in products* *We believe that the cumulative mass percentage of substances present in the product (Table 4, page 52 of the Technical Report 3.0) should include stricter requirements for the PLL category than for the ALL category rather than the situation proposed which is the opposite situation. We also believes that the new limit of 10% for non-degradable substances for TLL greases- is too strict compared with the limits in the current version of the Ecolabel standard where up to 25% of non-biodegradable materials are permitted. <u>There are mineral based thickeners (Bentonite), which are not biodegradable, but enivornmental friendly.</u>* *It is the opinion of the our members who are experienced grease manufacturers that it would be very challenging to produce a TLL grease that would meet these stricter requirements, and there is therefore the potential that no TLL greases would qualify for the ecolabel (examples of TLL greases include rail lubrication or rail-based lubrication)Instead of separating different types of grease we suggests that all greases should be required to meet the same criteria concerning the content of biodegradable, partially degradable and non-degradable substances. Furthermore, based on the experience of grease producing members the limits should be revised as follows:* • *"> 80%" for the "Readily aerobically biodegradable";* • *"< 20%" for the "Inherently aerobically biodegradable";* • *"< 20%" for the "Non-biodegradable and non-bioaccumulative".*	

For TLL-Greases max 10% inherently aerobically biodegradable and non-biodegradable and non-bioaccumulative raw materials can be used according to the proposed criteria. The most common thickener for greases is Li-12-hydroxystearate, which is rated as inherently aerobically biodegradable. About 10% are needed for a NLGI 2 grease. Most of the additives are inherently or non-biodegradable. This means for that kind of grease almost no additives can be used anymore. *Increase the limit value for inherently aerobically biodegradable and non-biodegradable and non-bioaccumulative raw materials of TLL-Greases*	
Please could you clarify this point from page 52 TR3.0- *…;* ***a minimum 5% of polymer is current use (polymers are excluded from biodegradability tests).*** *….* *Polymers are excluded from biodegradability test- Should this read that polymers are excluded form bioaccumulation tests and not biodegradability test?*	Polymers in general are not excluded from biodegradability test. In the text we refer to non-biodegradable polymers with inorganic base used as thickeners in some TLL greases. (e.g. bentonite or hectorite which are phyllosilicates). Text has been clarified accordingly.
"Inherently biodegradable includes nowadays also a 301-test based on CO2 generation or O2 depletion when 60% pass level is reached within 60 days. This comment by a stakeholder has been accepted by the JRC with the explanation that "despite is not specified in the text, other equivalent test methods different than those included in criterion text can be used". *We find that this proposal is not acceptable and cannot be verified by current guidance: For the OECD 301 tests a prolongation is considered as another category called "enhanced screening tests" which do not allow a categorization as ready biodegradable. When the pass level of an OECD 301 test is only reached after 60 days, the test item is considered as being "non-persistent". Only when results of ready biodegradability tests indicate that the pass level criterion is almost fulfilled (i.e. ThOD or DOC slightly below 60% or 70%) such results can be used as evidence for inherent biodegradability. This is also the case when the pass level criterion is fulfilled but the 10-day window criterion is not (see ECHA Guidance R.7b version 4.0, June 2017). Thus, a prolongation of a 301 test cannot be used as evidence for inherent biodegradability. A prolonged test gives information about non-persistency but not on inherent biodegradation.*	**ACCEPTED** Considering the provided clarification. The prolongation of OECD 301 cannot be considered equivalent to tests included for inherent biodegradability and shouldn't be accepted at application. A prolongation of a 301 test cannot be used as evidence for inherent biodegradability. In the UM, if other equivalents methods are indicated, OECD 301 should not be included
Statement: Readily biodegradable shall be measured in accordance with the following tests: Regulation (EC) No 440/2008 (Part C.4, C.5 and C.6 of the Annex), OECD 301, OECD 310, or equivalent methods. *It has been accepted that the OECD 306 marine biodegradation test method is suitable for measuring the ready biodegradability of a substance. For clarity and to avoid ambiguity, would it be possible therefore to specifically reference the OECD 306 test method as being acceptable in the text. The existing Ecolabel text references Part C.4 of the Annex to Regulation (EC) No 440/2008, OECD 306 and OECD 310 as acceptable test methods. Therefore please could the OECD 306 test method be specifically referenced in the text of the revised EU Ecolabel for Lubricants for measuring ready*	**ACCEPTED** OECD306 has been explicitly indicated in the text for Readily biodegradable measurement.

biodegradability? *The text would therefore read:- "Readily biodegradable shall be measured in accordance with the following tests:- Regulation (EC) No 440/2008 (Part C.4, C.5 in conjunction with C.6 and C.42 of the Annex), OECD 301, OECD 306, OECD 310, or equivalent methods.*	
The JRC has clarified that "despite is not included in the criterion text, the bioaccumulation potential has not to be calculated when a substance is biodegradable. If a substance is biodegradable is per se non-bioaccumulative. To avoid a complex criterion text the conclusion was to delete this part, as in the current decision text. User Manual could include this information. *It should be noted that this proposal is not in full agreement with the REACH guidance[63] where it is stated that: "Readily biodegradable substances are likely to be rapidly metabolised in organisms. However, the uptake rate may still be greater than the rate of the degradation processes, leading to high BCF values even for readily biodegradable substances. Therefore, ready biodegradability does not preclude a bioaccumulation potential. The ultimate concentration in biota (and hence bioaccumulation factors) will depend also on environmental releases and dissipation, and also on the uptake and metabolism and depuration rate of the organism. Readily biodegradable substances will generally have a higher probability of being metabolised in exposed organisms to a significant extent than less biodegradable substances. Thus in general terms (depending on exposure and uptake), concentrations of most readily biodegradable substances will be low in aquatic organisms and evidence of ready biodegradability may provide useful information in a Weight-of-Evidence approach for bioaccumulation assessment".*	**AKNOWLEDGE**

[63] Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance Version 3.0 June 2017.

We do not know if this new limit and new restriction will have an impact on the current LuSC list resp. the current approved substances. As we learnt it could happen that substances of the current LuSC list may only have results summarised as Log Kow > 7 (or > 7.5), simply because that was the limit of the test method and standards at the time the testing was conducted. If substances will loose their LuSC list status due to this fact, that could cause a significant restriction for the formulaton of EEL lubricants and in the worse case the loss of the EEL of currently approved lubricants. Without knowing the impact of the modified bioaccumulation limits we strongly recommend to postpone this approach until the impact on the number of possible substances (LuSC list) is known. Set the existing value of log Kow <3 or >7	
Bioaccumulation: has an octanol-water partition coefficient, log Kow, value of <3 or > 8, or Although earlier in the report it is claimed that the bioaccumulation criterion has not been changed this is incorrect, and the upper limit for LogKow has been incraesed from 7 to 8. It is claimed that only a low number of curent licences would be impacted by this change but it is difficult to reconcile this finding with our knowledge of the bioaccumulation characteristics of many substances that cite >7 as LogKow. It apppears that JRC is intent on making the ecolabel fate criteria as close to that of the Blue Angel as possible. For this reason it is proportionate to include a derogation for substances with existing LogKow data showing a result >7 to avoid those applicants having to retest those substances. The Blue Angel contains a derogation for substances with LogKow > 6.: *Bioaccumulation: has an octanol-water partition coefficient, log Kow, value of <3 or > 8*, or (* = applicants who can demonstrate that scientific data demonstrating LogKow >7 already existed for an ingredient before the date of entry into force of these criteria are eligible to apply for a derogation from this criterion, provding they can demonstrate that the component is critical to the performance of the finished fluid)*	**ACCEPTED** Considering the continuous opposition during the process from industry side and the uncertainty related to the impact on current licenses it is suggested to keep existing log log Kow values for this revision. However, for future revisions it is proposed to explore in detail data on current licenses with this regards at an early stage of the revision, in order to know with certainty the impact of introducing a lower upper limit in future revision.
Several industry stakeholders and associations *It is welcomed that JRC were receptive to many comments explaining why setting the upper limit at 10 was inadvisable from a practical viewpoint. However, they appear to have underestimated the practical impact of setting the upper limit at or above 8. Although an OECD method exists with an upper standard of 8.2, a significant amount of historical testing for Log Kow was carried out with the upper standard at 7. This means that there is a considerable amount of test data around for those ingredients that form the additive concentrate (i.e. the part of the lubricant which has a significant impact on the technical performance) where results are summarised as Log Kow > 7 (or > 7.5), simply because that was the limit of the test method and standards at the time the testing was conducted. There was logic in this because many experts regard the interval of concern for Log Kow as between 3 and 7 (or at an extreme 7.5). It is noteworthy that the Blue Angel recognises this as a practical matter and includes a derogation for non-degradable substances with Log Kow > 6 that can be demonstrated to be critical to the performance of the lubricant. We suggests that there is a need for a similar provision to be included in the revised ecolabel lubricants criterion to prevent ingredient suppliers having to retest their components*	

just to confirm that they meet this new criterion. If this request for a derogation was rejected, another practical solution would be to only enforce the > 8 upper limit of for a non-degradable substance that didn't have any existing bioaccumulation data at 1st January 2019, when the new requirement came into force. In this circumstance, it is reasonable that the applicant/supplier could develop Log Kow data in full knowledge of the new upper limit. Otherwise requiring applicants (or their suppliers) to retest is completely disproportionate, and could result in a loss from the market of useful chemistry.	
The upper limit logKow-value varied at each AHWG and technical document. This variation of the value and the reasons stated led to a lot of confusion which was also enlarged by the reasonings given. As starting point the CLP was considered but the bioaccumulation potential starts in the CLP at logKow=4. *Estimated log Kow values by any of these calculation methods < 4 or > 8 indicate that the substance is not expected to bioaccumulate.* *According to CLP Bioaccumuation potential start above logKow of 4. The text in general refers to CLP if it is to reduce values in the criteria but no change is made if the CLP has been more favourable compared to the DSD.*	
With regards the statement: Finally, available data from SDS has been considered to understand the impact of the modification in the upper threshold value of log Kow on the LuSC-list. If the upper limit is modified to 8, only 7% of the substances listed will be affected. In fact, half of the substances included in the LuSC-List have a log Kow <3 or >8 (see the distribution below). *The way the impact is set at 7% is unknown. It seems that 50% is more appropriate given the remark at the next sentence.* *The change on the threshold value entails still an impact on the LuSC-list that is difficult to assess.* *According to me 17 entries of the 72 from the non-base fluid entries of part 2 of the LuSC-list section indicate that the logKow is not determined. It is unknown if these are included in the 7% but 17 from 73 is already 23%.*	
Criterion 3 now specifies that biodegradation and where necessary bioaccumulation data is required for each intentionally-added or intentionally-formed substance at or above 0.10% in the final product. Intentionally-added substances includes impurities as per section 2. However, test data is usually generated on ingredients that contain low levels of impurities and so it would be disproportionate to expect applicants to generate separate fate data on impurities. Substances present in the product as an impurity will be specified in compositional disclosure (as function), and so it should be clarified (e.g. in the User Manual) that for the purposes of criterion 3 test data does not need to be generated separately for any impurity present in ingredients for which test data has been generated. REACH and associated guidance described substances : *For the purposes of criterion 3 test data does not need to be generated separately for any impurity present in ingredients for which test data has been generated*	**PARTIALLY ACCEPTED** In the general assessment and verification text it has been specified following: *For the purpose of criterion 1, impurities stated in the SDS should be treated as intentionally added substances* Therefore the statement only applies to criterion 1, thus test data does not need to be provided/generated separately on impurities.
Bioaccumulation: Threshold for measured BCF being used to derogate bioaccumulation testing has <u>not</u> been increased to <= 500 in line with CLP. In 1st AHWG BCF of <= 500 L/kg was suggested by JRC who recognised that <= 100 L/kg was extremely challenging to achieve. Our previous comment was met with the response that JRC changed its mind between 1st and 2nd AHWG meetings. Could we ask JRC to explain the scientific reason behind their decision to revert to this	In the first proposal the requirements to establish bioaccumulation of a substance were suggested to be modified according to the last version of CLP Regulation. In the 1st AHWG the following values

extremely conservative position, or reconsider their position and amend the criterion as originally suggested. : *Bioaccumulation: has a measured BCF of <= 500 L/kg*	were presented: log Kow value of < 4 or >7 and BCF of ≤ 500 L/kg. However, during the consultation process it was discussed and agreed to keep the current formulation of the criterion with the strict values of the BCF and the lower limit of log Kow and not to align them with the less strict threshold given in CLP Regulation. With regards the test method, note the text: The bioconcentration factor (BCF) shall be assessed according to Part C.13 of the Annex to Regulation (EC) No 440/2008 or equivalent test methods.
The Technical Report 3.0 indicates that BCF measurement is the method of choice for measuring the bioaccumulation potential of non-organic compounds, surfactants, and some organo-metallic compounds, and appears to suggest that no other method would be valid. JRC/Commission may be unaware that in vivo BCF studies are extremely expensive (e.g. due to the need for radiolabelling, very challenging analysis of low levels of test material etc) and typically have to be performed on a discrete chemical structure, not a mixture. Since many lubricant ingredients are characterised as UVCB substances, each constituent would need to be measured separately increasing the cost of this testing to an unrealistic level for qualifying a product for ecolabel. Finally, and perhaps most relevant, the BCF study OECD 305 is a vertebrate study and it is highly likely that regulatory approval would not be granted to an EU company for such testing for the purposes of qualifying for the ecolabel.	
Typo, bioaccumulation 3rd paragraph: *Estimated log Kow values by any of these calculation methods of <3 or >8 indicate that the substance is not expected to bioaccumulate*	**ACCEPTED**
Typo: (more information in the separated ANNEX: Table of comments)	
Table 4. Column header for TLL greases : *Typeface needs to be white rather than blue*	
Typo, biodegradation 3rd paragraph: *In case of a comparison with a fragment not included here above, adequate and reliable documentation……*	
Several references to Nordic Swan in rationale of proposed assessment and verification: *Omit references to Nordic Swan since no longer includes a lubricant category*	
Typo, outcomes from and after 2nd AHWG meeting, 2nd paragraph: *(more information in the separated ANNEX: Table of comments)*	
Typo, outcomes from and after 2nd AHWG meeting, 7th paragraph: *One stakeholder commented that BCF value should be less restrictive;*	
Typo, outcomes from and after 2nd AHWG meeting, 7th paragraph: *(more information in the separated ANNEX: Table of comments)*	
Typo, summary, first bullet: *There is no evidence that a substance with higher values of 7 is not bioaccumulative. For higher values of log Kow the uncertainty related with estmation methods may vary.*	
It is worthwhile to note that the cumulative mass percentages on biodegradation has become quite more lenient in the proposed criteria than in the current criteria document. *No change proposed* *With these fractions the ecolabel moves away from biodegradation as most important criteria.*	**ACCEPTED**

We appreciate the fact that the information submitted by us was considered for current evaluation on the impact of proposed criteria. We would, however, once again like to advocate for setting the criteria limit toward log Kow value of <3 or > 7. Most of our current assessments/testing was done setting the log Kow with the upper standard at 7. *Once again, like impact analysis done for H phrases, the evaluation should be broken down and assessment (i.e. impact analysis) done separately for Base fluids, Thickeners, Additives and Polymer systems.* *The additional statement that impurities are to be considered as intentionally added substances, means that further testing is required for every impurity. Executing BCF study (OECD 305) requires previous approval from ECHA.*	**ACCEPTED**
With respect to the bio-accumulation potential (page 53), the following criteria are set: The (potential) bioaccumulation does not need to be established when the substance: – has a MM > 800 g/mol, or – has a molecular diameter > 1,5 nm (> 15 Å), or – has an octanol-water partition coefficient, log K_{ow}, value of <3 or > 8, or – has a measured BCF of ≤ 100 L/kg, or – is a polymer and its molecular weight fraction below 1.000 g/mol is less than 1 %. *→ In case substance fulfills the requirement that the molecular diameter is > 1,5 nm, but the measured log Kow value is between 3 and 8, which data point is considered to be relevant? If "the molecular diameter is > 1,5 nm" criteria is fulfilled, would this allow that the product is not regarded as bio-accumulative?*	In the case any of the points is accomplished, the substance would be exempted from bioaccumulation potential.
Within the Technical Report 3.0, the following is stated: Log Kow values are applicable to organic chemicals only. To assess the bioaccumulation potential of non-organic compounds, surfactants, and some organo-metallic compounds, BCF measurements shall be carried out. – page 53 *→ It seems that the BCF measurement is the method of choice, and can overrule values obtained by other methods. Please consider the comment made above with regard to the molecular diameter, etc. where further clarification is needed.* *It should be considered that the BCF studies are expensive (e.g. radiolabeling, specific analysis) and should be done with a single substance, not a mixture. Most of additives are UVCB substances. Each constituent would need to be measured. Even more so, as the current criteria suggest considering impurities as intentionally added substances. The BCF study (OECD 305) is a vertebrate study (fish) which needs an approval for animal testing like the tests with mammals (mice, rates …).*	Impurities only relevant for criterion 1, clarified

Third proposed Criterion 4: Origin, traceability and advertising of renewable raw materials

Comments	JRC Dir. B response
Does the criteria concern all kind of raw materials (even synthetic esters) which are used in the final product? *There is no renewable calculation anymore? The minimum content will be 25% for all categories? How*	**CLARIFIED** There is no requirement on a minimum renewable content.

should licence holders proceed to validate this criterion (specific tests?)?	The criterion consist on the following subrequirements (ONLY in case RENEWABLE ingredients are used): - Reporting requirement in case renewable ingredients are used (Type, origin, certification schemes (if used)). - Only in the case that palm oils is used, a minimum content of certified palm oils is requested. - For the term "bio" to be used in the product, the minimum bio-based carbon content in the final product shall be 25% in accordance with EN 16807:2016 and this should be tested with any of the following: ASTM D 6866 or DIN CEN/TS 16137 (SPEC 91236):2011-07 or EN 16640:2017 or EN 16785-1:2015 or other equivalent test method.
Comment of a licence holder : *"In the case of synthetic esters, the way in which they are considered, which influences the criteria that must be applied to them, does not seem clear to me. Are these synthetic products, just like PAOs or PAGs? Or should they be considered as (partially) renewable products because they can contain a certain amount of carbon of renewable origin, in which case they are subject to criterion 4?* *- where appropriate, it does not seem to me easy to find on the market of fatty acids of Palm origin answering the RSPO "mass balance", the other options "segregated" and "identity preserved" up to date utopia in my opinion for the fatty acids used in lubrication"*	**CLARIFIED** The criterion applies to all renewable raw materials including vegetable oil-based synthetic esters.
It could be preferable to add the most recent European test method for bio-based content in the sentence : *"To demonstrate compliance with 4 (b) the applicant shall enclose the final product test report in accordance with ASTM D 6866 or DIN CEN/TS 16137 (SPEC 91236):2011-07."* *The sentence could be :* *"To demonstrate compliance with 4 (b) the applicant shall enclose the final product test report in accordance with ASTM D 6866 or DIN CEN/TS 16137 (SPEC 91236):2011-07 or EN 16640:2017*	**ACCEPTED** The most recent European test method (*EN 16640:2017)* for bio-based content has been added.
In the sentence, *"If the term "bio" is used, the minimum bio-based carbon content in the final product shall be 25% in accordance with CEN/TR 16227:2011 "* *It could be preferable to add the obligation to mention also the test method.* *The sentence could be :* *"If the term "bio" is used, the minimum bio-based carbon content in the final product shall be 25% in accordance with CEN/TR 16227:2011 and the test method used to measure the bio-based content shall be*	**REJECTED** This information would be available in the application as the report shall be provided. It is not considered relevant to ask producers to include information on the method on the product as is not relevant to consumers. How the product is marketed is responsibility of the producer.

declared on the product "	
The ISO 16785 standards are not relevant?	**ACCEPTED** The most recent European version of the test method (*EN 16785-1:2015)* for bio-based content or equivalent has been added. EN 16785-1:2015 [*Bio-based products - Bio-based content - Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis*]
According to criterion 4b) the applicant shall enclose the final product test report in accordance with ASTM D6866 or DIN CEN/TS 16137 (SPEC 91236):2011-07 (Plastics. Determination of bio-based carbon content). We suggest to add phrase "EN 16640 or other equivalent test method" as below: • *Current version:* **To demonstrate compliance with 4 (b)** the applicant shall enclose the final product test report in accordance with ASTM D 6866 or DIN CEN/TS 16137 (SPEC 91236):2011-07. • *Proposed change:* **To demonstrate compliance with 4 (b)** the applicant shall enclose the final produ report in accordance with ASTM D 6866 or DIN CEN/TS 16137 (SPEC 91236):2011-0 **or other equivalent test method** *This European Standard (EN 16640:2017Bio-based products - Determination of the bio-based carbon content of products using the radiocarbon method) specifies a method for the determination of the bio-based carbon content in products, based on the ^{14}C content measurement (radiocarbon analysis the same as ASTM D6866). This European Standard also specifies three test methods to be used for the determination of the ^{14}C content from which the bio-based carbon content is calculated: -* – *Method A: Liquid scintillation-counter method (LSC) (normative);* – *Method B: Beta-ionization (BI) (informative);* – *Method C: Accelerator mass spectrometry (AMS) (normative).* *The bio-based carbon content is expressed by a fraction of sample mass or as a fraction of the total carbon content. This calculation method is applicable to any product containing carbon, including bio composites. However this European standard does not provide the methodology for the calculation of the*	**PARTIALLY ACCEPTED** *EN 16640:2017 [Bio-based products - Determination of the bio-based carbon content of products using the radiocarbon method]* EN 16640 and other additional methods have been Included. Other equivalent methods are accepted as specified in the general assessment and verification text for each EU Ecolabel Decision. Therefore the text "other equivalent methods" has not been repeated in this specific section.

biomass content of a sample, but issue is covered by EN 16785-1:2015 [Bio-based products - Bio-based content - Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis] and EN 16785-2:2018 [Bio-based products - Bio-based content - Part 2: Determination of the bio-based content using the material balance method].	
Term "bio": If it is used where? *Include in criterion 8 that the product "meets the requirements as a biolubricant according to CEN/TR 16807:2017" instead of the third remark. Alternatively it can also substitute the second remark.* *The 25% refers also to the CEN/TR 16807 and not to CEN/TR 16227:2011.* *Since the term bio is used (as biolubricant) it needs to be indicated where it can be applied. The CEN document states as well that any current ecolabelled lubricant automatically qualifies as a biolubricant.*	**CLARIFIED and PARTIALLY ACCEPTED** **According to** *"DIN CEN/TR 16227; DIN SPEC 51523:2011-10: Liquid petroleum products - Bio-lubricants - Recommendations for terminology and characterisation of bio-lubricants and bio-based lubricants"* term "bio" means a product minimum content of 25% renewable ingredients. In line with this standard and Blue Angel scheme, the revised criteria includes a requirement asking that for those applications claiming to be "bio" to prove that the minimum 25% is accomplished. Therefore a product with the revised EU Ecolabel can be marketed/advertised as "bio" only if the minimum 25% is proved. With regards to reference to EN 16807:2016, this correction has been made as the EN 16807:2016 was developed from CEN/TR 16227:2011 (a technical report). CEN/TR 16227:2011: Liquid petroleum products. Bio-lubricants. Recommendation for terminology and characterisation of bio-lubricants and bio-based lubricants EN 16807:2016: Liquid petroleum products - Bio-lubricants - Criteria and requirements of bio-lubricants and bio-based lubricants
To use the term "bio" if only 25% of the final product is bio based carbon seems to be very strange.	
We doubt that is a good proposal setting the threshold at 25% of biobased content to allow the use of the term "bio" on the lubricant. Producers should declare the real content behind the product and inform whether it is 50 % bio based or 80% or far less. A product should at least be 50% bio based to make the extra claim. Otherwise the requirement might support green washing if allowing to claim the bio content at so low concentrations.	
Is the right citation used for bio-based lubricants?: *If the term'bio' is used, the minimum bio-based carbon content in the final product shall be 25% in accordance with CEN/TR 16807:2017*	
As the requirement above is worded it is no requirement. "Preferentially" means nothing.	**ACCEPTED**
"May preferentially ..." cannot be used as a requirement. A different formulation needs to be used or the requirement should be removed.	

Several CBs claimed that 100% certified palm oil ingredients should be requested in case of use of palm oil as ingredients. This is in line with other PGs and would not have an impact in current licences as there are no licences using palm oil. This would prevent the use of non-sustainable palm oil. *For palm oil we would like to raise the threshold to 100%.* *Thus only 25% of the total fraction of Palm oil or Palm Oil Kernel used in the lubricant must be certified?* *If only 25% must certified I suggest to apply at least mass balance method of certification of Palm Oil* *If only 25% must be certified and therefore not 75% I would increase the certification demands and leave out the Book and Claim method.*	**ACCEPTED** An increase of the percentage of (w/w) of the palm oil renewable ingredients from 25% to 100% is proposed. This increase is because several Competent Bodies asked to increase the value to 100% in line with detergents product group. In addition, they mentioned that the number of available licences suggests that palm oil is not of relevance and hence requesting 100% certified palm oil ingredients would not significantly impact the number of available licences, the increase to 100% is considered feasible. Several licence holders have been further contacted with this regards. Although a manufacturer prefers to have a flexible requirement (keeping the 25% proposal), another manufacturer considered it easier for them to manage their supply chain and manufacturing with the value set at 100%. Based on this all the palm oil supply chain models proposed in the criterion are retained.
Our organization welcomes that there is no minimum mandatory content on the renewable origin of materials. *The requirement of the sustainability of only on Palm Oil is unambitious. 25% of palm oil with sustainable origin seems very low. It is also unclear whether the book and claim model is acceptable. On the one hand it is stated that only identity preserved, segregated and mass balance can be used to demonstrate compliance. On the other hand, it is also indicated that GreenPalm certificates can be provided to demonstrate compliance to the Book and Claim model.* *We highly recommend that only traceable palm oil is accepted. This includes identity preserved and segregated palm oil. The use of the Book and Claim supply chain system has a very low level of traceability and does not provide sufficient guarantee that the palm oil is sustainable and that it is not destroying forests and potentially triggering conflict in local communities.*	An increase of the percentage of (w/w) of the palm oil renewable ingredients from 25% to 100% is proposed. This increase is because several Competent Bodies asked to increase the value to 100% in line with detergents product group. In addition, they mentioned that the number of available licences suggests that palm oil is not of relevance and hence requesting 100% certified palm oil ingredients would not significantly impact the number of available licences, the increase to 100% is considered feasible. Several licence holders have been further contacted with this regards. Although a

If renewable ingredients are used they must be traceable and in the case of palm oil or palm kernel oil, or derived from palm oil or palm kernel oil, the applicant must provide evidence through third-party chain of custody certificates that the input materials used in the manufacturing originate from sustainably managed plantations. Roundtable for Sustainable Palm Oil (RSPO) certificates or certificates of any equivalent or stricter sustainable production scheme demonstrating compliance to any of the following models; identity preserved, segregated, mass balance shall be accepted. *Book and Claim Model must not be accepted.* *Otherwise the use of Palm oil, kernel oil and their derivatives should be banned.*	manufacturer prefers to have a flexible requirement (keeping the 25% proposal), another manufacturer considered it easier for them to manage their supply chain and manufacturing with the value set at 100%. Changes have been made to the wording of the text to reflect the changes made to the RSPO supply chain models as of 1st January 2017, when RSPO Credits replaced GreenPalm certificates, and also the market situation described. The criterion proposal recognizes all the available RSPO supply chain models including the book and claim model. The book and claim model is accepted as it is the principal trading model employed by oleochemical and chemical industries for acquiring RSPO Credits of derivatives of palm oil and palm kernel oil,. Recognizing only the physically traceable supply chain models will limit the ability of manufacturers to source these materials for the purpose of this ecolabel. Although it does not offer physical traceability, the amounts of RSPO credits purchased and claimed can be verified using the online traceability system - the RSPO Palm Trace system. Moreover, the book and claim model directly supports RSPO certified growers and farmers. It also allows organisations to support sustainable palm oil instantly despite complicated supply chains or the use of complex palm and palm kernel fractions and derivatives. For these reasons, it is retained.
As commented previously, the reference to the EU Renewable Energy Directive appears force-fitted and has little obvious relevance to a certification scheme for bio-baed ingredients used to produce lubricants. We suggest that this entire section is removed from the 3rd technical report down to the paragraph on page 65 beginning Table 3.12 shows.....: *Delete all references to the EU Renewable Energy Directive*	**REJECTED** Some voluntary sustainability certification schemes (e.g. ISCC) currently operating in the market and applied to the certification of bio-based materials (e.g. rapeseed oil) used in bio-based applications, were developed in response to the European Union Renewable Energy Directive (RED) 2009/28/EC. Therefore the EU Renewable Energy Directive is relevant as it forms the basis for some of the certifications schemes for bio-based ingredients used to produce lubricants as there

	are examples of lubricant producers who have applied certification scheme(s) originating from it (e.g. ISCC Plus) to the certification of renewable raw materials(e.g. Crude Palm Oil, Palm Fatty Acid distillate). Moreover, as the section based on the reasoning presented above forms the rationale of previous versions, the section and accompanying table are retained.
Bioliquids produced from wetlands, continuously forested areas, land with mature trees refer to specific types of bioliquids like palm oil, coconut oil and possibly soja oil but not from rape oil, animal fats etc. *-remove reference to the RED Directive from the Technical report.* *-It would have been much better if a clear distinction would have been made between the different vegetable oils and their source, the mineral oils and synthetic ols from mineral oils instead of a chapter on vegetable oils only.*	**REJECTED** Some voluntary sustainability certification schemes (e.g. ISCC) currently operating in the market and applied to the certification of bio-based materials (e.g. rapeseed oil) used in bio-based applications, were developed in response to the European Union Renewable Energy Directive (RED) 2009/28/EC. Therefore the EU Renewable Energy Directive is relevant as it forms the basis for some of the certifications schemes for bio-based ingredients used to produce lubricants as there are examples of lubricant producers who have applied certification scheme(s) originating from it (e.g. ISCC Plus) to the certification of renewable raw materials (e.g. Crude Palm Oil, Palm Fatty Acid distillate). Moreover, as the section based on the reasoning presented above forms the rationale of previous versions, the section and accompanying table are retained. An additional chapter to make the distinction proposed is not considered useful as it reintroduces rather general information into the technical report.
Typo, 5th paragraph: *It is the raw material supplier that needs to be certified, not the lubricant producer company*	**ACCEPTED**

The suggestion in the 7th paragraph that including additional requirements for ecolabelled products that are bio-based will ensure that they are produced and marketed according to the ecolabel standard and that this will guarantee a good use of the term bio is completely contradictory to the decision to delete the requirement that ecolabel lubricants should contain a minimum amount of bio-based carbon from renewable sources : *This sentence should be removed from the report to avoid accusations that this section of the report contains contradictory information*	**REJECTED** According to "CEN/TR 16227:2011: Liquid petroleum products. Bio-lubricants. Recommendation for terminology and characterisation of bio-lubricants and bio-based lubricants", the term "bio" means a product with a minimum content of 25% renewable ingredients. In line with this standard and Blue Angel scheme, the revised criteria includes a requirement asking that for those applications claiming to be "bio" to prove that the minimum 25% is accomplished. Therefore a product with the revised EU Ecolabel can be marketed/advertised as "bio" only if the minimum 25% is proved.
Concerning renewable raw materials, would it be possible to have a list of accepted certification, competent bodies, laboratories?	**ACCEPTED** It is suggested to include additional information on the different existing certification schemes in the User Manual.

Third proposed Criterion 5: Packaging/container requirements

Comments	JRC Dir. B response
A reduction in the consumption of fresh plastics is useful and desirable and should be sought especially for ECO label products. Nonetheless, there are no variants with the desired content of post-consumer recycled plastic in the current packaging market for most common containers. In most cases, the B2B products are filled in containers that are also suitable for transporting dangerous goods (UN approval). According to our research, there are currently no plastic packaging with recycled content for this packaging category. It is unlikely that the time until enforcement of the criteria will be sufficient to develop suitable packaging together with the packaging material manufacturers	EU Ecolabel criteria for Computers and Furniture have made the first attempt, recently included requirements on this, moreover recycled materials in packaging are promoted in EU Ecolabel criteria for rinse-off cosmetics, and in all 6 criteria sets for Detergents and Footwear, therefore Lubricants shouldn't be an exclusion, taking into account the recent communication of the Plastics Strategy in Circular economy. To further support the integration of recycled plastics in the market, the Commission will also explore more targeted sectoral interventions. In the context of future work on the Packaging and
This draft criterion seem to be too restrictive for manufactures, french licence holders are really reluctant because it will lead too many costs and they would think serously to maintain or not the certification of their products, we could lost more than 25 products in France! Here are the comments : "In terms of packaging: we are surprised it is always mentioned that plastic packaging must contain 25% recycled raw materials. (pro and particular) To our knowledge as already mentioned, this technology currently exists only on small packages 1l max, not on IBC / containers. It was noted that this remark was taken into account but still maintained. We are perplexed by the technical feasibility." *"One point is very restrictive for us is the part on packaging that would require us to change the packaging for ECOLABEL products which will generate additional costs by always increasing the price of the finished product (25% recycled material*	

for plastic and a special closing system). This will lead us to ask the question of what is our aim in this label, on which our customers do not ask for."	Packaging Waste Directive, thought will also be given to using economic instruments to reward the use of recycled content in the packaging sector. Finally, the Commission will work on integrating recycled content in Green Public Procurement criteria.
Our association agrees that a reduction in the consumption of fresh plastic is desirable, and fits well with the overall goal of the EU ecolabel scheme. Nonetheless, from a practical standpoint, our members are not aware of any EU packaging suppliers who currently offer the desired content of post-consumer recycled plastic for most common containers. Additionally, for internal logistic reasons B2B products are sometimes packaged in containers and drums that are also suitable for transporting dangerous goods (i.e. have United Nations approval). Again, our members are not aware of any plastic packaging with recycled plastic content that also meet UN container standards, and we consider that there is insufficient time to work with packaging material manufacturers and so we are very concerned that no suitable containers will be available by the implementation date of the new criteria.	
We do not know if such packaging material is available commercially and under which conditions. Moreover this request will for sure increase the costs because additional packaging material has to be handled. Moreover such a new plastic material has to tested thoroughly to guarantee long term compatibility with the fluids and no negative influence on the properties of the fluids. Without any confirmation that packaging material has been tested and can be approved for intended use we cannot support the approach to request 25% of recyled plastic. *Moreover, we are astonished that for packaging a minimum quota for the used material is provided, but not for the lubricant itself! Think of the availability of recyled materials*	
I would like to note the following about CRITERION 5 (chapter 3.6 Packaging requirements) and ask you for a short explanation of this point: *Under b) a design is prescribed, which m. E. very vaguely formulated:* *1. How should such a dispenser system look like? Here, instructions / suggestions should be made.* *Is this meant a metering mechanism that only pours a certain amount? Then this is very impractical, since the forest worker for instance with gloves and this construction should fill his chain oil tank.* *The worker will therefore first unscrew this dispenser system and fill his tank on the chain saw directly or his personal double canister as usual.* *If the dispenser system is to be understood merely as an outlet mechanism, then the forest worker can fill his chain saw in a more targeted manner. However, this assumes that the extraction mechanism works over the life of the container.* *The extract would also have to retract or unscrew, so you can safely close the bottle / container.* *In the past, such technical aids have only caused problems with respect to the robust handling in the forest and the life of these plastic attachments.* *The forest worker gets rid of these difficulties by refusing such systems.* *The packaging and thus the product become more expensive, technical refinements are more prone in use and during*	**ACCEPTED** With regards the criterion on the dispenser, the intention of the design is principally to avoid accidental spillages during use, using as example, closure with a lower diameter or extensions allowing dumping the entire product when used. On the other hand, this requirement is not intended developing new strategies or dispenser closures; it only pretend to ensure that all the certified products have a dispenser to avoid spillage, as prolongation systems or narrow apertures. In order to avoid misunderstandings and misinterpretations, it is proposed to reword the text and to eliminate the word DISPENSER (since it may

storage / transport. *There is enough evidence on the packaging that the oil must not be spilled to the forest floor unused. Technical systems intended to prevent this are only useful for hazardous substances household detergents or similar)* *2. Subheading b) ... a dispenser closure system avoiding spillage shall be made available to the users ...* *Does it mean that the packaging requirement discussed above is a "can" requirement? Manufacturers and retailers can continue to use the existing, proven, user-friendly packaging?* *3. The ECO label is fully committed to environmental protection and resource conservation. With regard to these aspects, the additional use of a plastic dispenser is contradictory. The acceptance of this pouring device by the forest workers is not given.* *It creates additional plastic waste that complicates handling in the forest, during transport and storage.* *Therefore I ask you for a concrete technical description of the required dispenser system (obligatory / optional for containers in forestry work?).* *I would be pleased if my objections lead to reconsidering the packaging requirements.*	wrongly refer to an extra component allowing dosing).
After talking with my applicants I have a question what you mean with dispenser system. A dispenser is a gadget where you can get a certain amount of product out of the canister. *Let's imagine the practical use of for example chain saw oils. You usually refill the oil in the chain saw but you never know how much you will need. It depends 1. on the type of chainsaw you use and 2. on how much is still in the tank. So a dosage system will not work. I could imagine that a filler neck as adapter which you can screw on top of the canister might work and help to avoid spillage (see here for example: https://www.stihl.de/STIHL-Produkte/Zubeh%C3%B6r-und-Betriebsstoffe/Kraftstoffe-Schmierstoffe-Kanister/Kanister-und-Einf%C3%BCllsysteme/21717-1742/Ausgiesshilfen-f%C3%BCr-S%C3%A4gekettenhaft%C3%B6l.aspx or here: https://www.kettensaegen-saegeketten.de/forst/oele-fette-zubehoer/kanister/ausgiesser/).* *But obviously that is provided by the chainsaw manufacturer or the producer of the combi canisters with one that for the oil and one tank for the fuel (https://www.husqvarna.com/de/ersatzteile-zubehor/kraftstoffkanister/kombikanister/505698000/).* *From my experience the loggers do use the combi canisters a lot, since they only have one canister for fuel and oil to carry.* *So I have the feeling that forcing the lubricant producers to add additional dispenser systems to their canisters would just result in additional effort and waste production, since the loggers would just continue using their combi canisters or filler systems provided by the chainsaw manufacturers and wouldn't use the extra systems anyway.* *Could you clarify the wording please and tell me what you exactly had in mind as dispenser system? Please also consider what I wrote above.*	
Post-consumer recycled plastic should be defined according to standard ISO 14021 and usage of terms recycled content.	**PARTIALLY ACCEPTED** There are no methods available for directly measuring recycled content in a product or packaging. Usage of terms and evaluation methodology with regards recycled content included in ISO 14021:2016
Criterion 5 refers to B2C sales which is within the current scope of minor relevance. In addition the 25% recycled fraction is not verified. *Include a verfication method of the 25% recycled plastic.*	

Since the impact is only on B2C use and since the scope excludes these type of lubricants to a very large extend it is suggested to include already a verification scheme already.	Environmental labels and declarations -- Self-declared environmental claims (Type II environmental labelling) has been reflected in the text.
In Nordic Swan we have a big problem with verification of the criterion on recycled content. The assessment and verification needs to be specified much more in detail.	
Is it possible to provide a list of suppliers for this feasibility?	
Reference to Nordic Swan should be deleted from this report because Nordic Swan no longer includes lubricants as a Product Group: *At least one regional eco-label includes information about the design of the packaging: NF-Environment includes a criterion on design to prevent the retention of the lubricant and also for the right dosing of lubricants*	**ACCEPTED**
Typo, Outcomes from and after 2nd AHWG meeting, 5th paragraph: *Finally, during the 2nd AHWG meeting, some stakeholders suggested to include a requirement concerning the presence of SVHCs in the packaging*	
Typos, Further research and main changes, 1st paragraph: *14 stakeholders were consulted, and only 5 responses were received about take-back system: 3 of them answered that they do not have a take-back system for packaging waste.*	
Typos, 2nd paragraph: *This criterion is considered relevant in terms of the circular economy, the level proposed is quite conservative and no technical evidence of existing limitations has been received.*	

Third proposed Criterion 6: Minimum technical performance

Comments	**JRC Dir. B response**
Chainsaw oils. A reference is needed for the 'KWF test'	**PARTIALLY ACCEPTED**

I am pleased to say that the Poland welcomes the most of the proposed changes in technical performance requirements. We are pleased to see that for chainsaw oils the KWF test document is referred directly, however we would like to have some comments on it. *In the KWF-test document some of the test method other than ISO or EN are referred. The ISO and EN standards or at least test method having the repeatability and reproducibility verified based on round-robin-test shall be referred. In our opinion each test method shall have specified precision according to ISO 4259. It is important in case of discrepancy of the results obtained by two different laboratories. The good practice is then to conduct the arbitration research and when the test method does have not specified precision such arbitration research cannot be done. We propose to revise the KWF-test method and where it is possible to refer the ISO, EN or EN-ISO standards or add some more precise information:* 1. *for test methods referred as KWF-method Appendix 1 "Cold temperature flow characteristics" we propose to change into ISO 3016 "Petroleum products -- Determination of pour point" or ASTM D 97 "Standard Test Method for Pour Point of Petroleum Products".* *The ISO 3016 gives a method for the determination of the pour point of petroleum products. Also describes a separate procedure suitable for the determination of the lower pour point of fuel oils, heavy lubricant base stock, and products containing residual fuel components.* 2. *for test methods referred as KWF-method Appendix 2 "Ageing resistance" we propose to change into DIN 51524 "Baadera test, 100-h storage at 80^{o}C "* 3. *for test methods referred as KWF-method Appendix 3 "Phase separation" we propose to change into ISO 6614 Petroleum products -- Determination of water separability of petroleum oils and synthetic fluids". It Specifies a test method for measuring the ability of petroleum oils or synthetic fluids to separate from water at a specified temperature (the normal test temperature is (54 ± 1) °C, but this may be increased to (82 ± 1) °C for products with a viscosity above 90 mm^2/s at 40 °C, and other test temperatures may also be specified).* 4. *for test methods referred as KWF-method Appendix 6 "Chainsaw soiling" we propose to change into ISO/TS 19858 "Forestry machines -- Portable chain-saws -- Test method for evaluating saw chain oil lubricity"* 5. *for test methods referred as KWF-method Appendix 7 "Odour development" we propose to change into ISO 5496 (Sensory analysis -- Methodology -- Initiation and training of assessors in the detection and recognition of odours) or ASTM D 1833 "Standard Test Method for Odor of Petroleum Wax"* 6. *the test method referred as KWF-method Appendix 5 "Staining clothes" (test laboratory) requires strict standardization.* 7. *the test method referred as KWF-method Appendix 4 "Contact materials" (field test) and Appendix 5 "Staining clothes" (field test) requires strict standardization.* 8. *the test method referred as KWF-method Appendix 8 "Labelling": it is doubled requirement not needed due to the fact that requirements on labelling are covered by new project of ecolabel criteria for lubricants.* *The Polish Competent Body welcomes the significant progress which has been made in the area of chainsaw oils. However some of the proposed solutions need the improvements. This include, in particular, those test methods that do not include determined the precision (having the repeatability and reproducibility). We do realize of the complexity of the problem and*	In addition, to avoid issues with regard the lack of repeatability and reproducibility of other methods than ISO or EN it has been added the possibility to demonstrate compliance with ISO/TS 19858"Forestry machines -- Portable chain-saws -- Test method for evaluating saw chain oil lubricity"

we are opened to the possibility of obtaining other opinion or arbitration. As an arbitration unit, we propose a Standardization Body, e.g. DIN (Deutsches Institut für Normung).	
As s general comment we would like to support the position that test methods shall include determined the precision (having the repeatability and reproducibility) specified according to ISO 4259 Petroleum and related products -- Precision of measurement methods and results -- Part 1: Determination of precision data in relation to methods of test. It is important in case of discrepancy of the results obtained by two different laboratories. The good practice is then to conduct the arbitration research and when the test method does have not specified precision such arbitration research cannot be done. *During the discussion on the draft of the Technical report for lubricants presented while on last CB Forum meeting, it turned out that there is a new version of KWF-test document of 2017 and it is available only in German language. The comments on new Ecolabel lubricant criteria sent previously concerned the KWF-test document of 2016 version. We are not able to give now the new comments on this document. As it was said on the last CB Forum meeting we propose to add the sentence „ or fit for purpose demonstrated preferentially by at least one relevant OEM approval based on ISO/TS 19858" as below:* • *Current version:*	

Table 5. Minimum technical performance for lubricant products **Lubricant category** / **Minimum technical performance** Chainsaw oils / KWF test • *Proposed change:* **Table 5. Minimum technical performance for lubricant products** **Lubricant category** / **Minimum technical performance** Chainsaw oils / KWF test **or „fit for purpose demonstrated preferentially by at least one relevant OEM approval based on ISO/TS 19858"** *I am pleased to say that Poland welcomes the most of the proposed changes in technical performance requirements. However some of the proposed solutions need the improvements. This include, in particular, those test methods that do not include determined the precision (having the repeatability and reproducibility). We do realize of the complexity of the problem and we are opened to the possibility of obtaining other opinion or arbitration.*	
For enclosed gear lubricants the primary performance test should be the pan-EU ISO 12925 standard (typo: should be ISO 12925-1) rather than the German DIN 51517 standard as the EU ecolabel is a pan-EU environmental standard. The German national DIN standard should be described as an alternative method. : *Enclosed gear oils: ISO 12925-1 or DIN 51517 section (I, II or III) as an alternative*	**ACCEPTED**
For fire-resistant hydraulic fluids only tables 2 to 5 for ISO 15380 are relevant for technical performance: *Fire resistant hydraulic fluids: ISO 15380 (Tables 2 to 5) + ISO 12922 (Table 1 to 3) or Factory Mutual Approval*	**ACCEPTED**
Why do the minimum technical performance requirements for temporary protection against corrosion and greases for this application include both a prescribed standard (ISO/TS 12928:1999) and the need for an OEM approval. The need for OEM approval was limited to those applications without a specific standard or test against which to qualify performance: *Delete 'Fit for purpose demonstrated preferentially by at least one relevant OEM approval based on'*	**PARTIALLY ACCEPTED** The wording has been partially amended reflecting that current User Manual guidance for 'fit for purpose' includes client applicants approval as a proof of verification for fit for purpose.
It is not stated in the verification section what is a RELEVANT OEM. *Remove the word relevant from Table 5 at page 76*	
It is either based on a specific ISO/TS or if fit for purpose only, OEM approval. *Remove OEM approval if a ISO/TS document exisits for the specific type of lubricant.*	
Lubricating greases: All other greases - Fit for purpose demonstrated preferentially by at least one relevant OEM approval. Our grease expert has suggested that this sub-category can be assessed in terms of meeting certain minuimum	**ACCEPTED**

performance standards by assessing compliance againt ISO 12924. ISO 12924 Lubricants, Industrial oils and related products (Class L) – Family X (Greases) specifies the requirements of greases used for the lubrication of equipment, components of machines, vehicles, etc. The purpose is to provide guidance to suppliers and end users of greases and to equipment manufacturers of grease-lubricated equipment. This ISO standard contains detailed test methods and requirements to meet the classification as a lubricating grease and is intended to be used in association with ISO 6743-9.: All other greases: ISO 12924	
Typos, Assessment and verification: *For those categories where fit for purpose is requested, it shall be preferentially demonstrated through at least OEM approval.*	**PARTIALLY ACCEPTED**
The need to produce a test report in the absence of OEM approval is confusing and should be clarified: *Where the minimum technical performance is demonstrated by testing against a specific standard or test method, the test report shall be provided*	
Rationale of the proposed criterion text - a) Total loss systems, 2nd paragraph. Another application should be provided for 'other not specified TLL' instead of wire ropes because wire ropes are specified in table 5	
Rationale of the proposed criterion text - i) Lubricating greases, 3rd paragraph: *For stern tube greases minimum technical performance was maintained in the form of 'fit for purpose' (under 'other greases')*	
Typos/suggested clarification in text. Further research and main changes in the third proposal, 3rd paragraph: *For those categories where fit for purpose is requested, it shall be preferentially demonstrated through at least OEM approval. Where the minimum technical performance is demonstrated by testing against a specific standard or test method, the test report shall be provided*	
I have a major issue with the Third proposal for criterion 6: Minimum technical performance. "In the third revision, it was decided that in order to run tests to prove compliance on a specific technical performance, only reports from third party independent accredited laboratories should preferentially be accepted as requested in the general assessment and verification text." This was discussed, but not decided on the video meeting. It is a very dangerous requirement for the EU-ecolabel, because of the high costs of the external testing. For example to fulfill DIN 51825 with a bearing grease will cost more than 10 k€ by my quick, rough calculation. Even big OEM`s accept company laboratory data if the internal laboratory fulfills ISO 9001. This preferability of external laboratories will increase the costs of EU ecolabel very much and jeopardize the profitability of the business opportunity. This could turn the interest of the industry away from the EU ecolabel.	The following text included in the general assessment and verification text is horizontal text for all product groups: *Competent bodies shall preferentially recognise attestations which are issued by bodies accredited in accordance with the relevant harmonised standard for testing and calibration laboratories (General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)) or with the principles of Good Laboratory Practice (GLP); and verifications by bodies that are accredited in accordance with the relevant harmonised standard*

	for bodies certifying products, processes and services. Accreditation shall be carried out in accordance with Regulation (EC) No 765/2008 of the European Parliament and of the Council[64]*.* *Where appropriate, test methods other than those indicated for each criterion may be used if the competent body assessing the application accepts their equivalence.* *Where appropriate, competent bodies may require supporting documentation and may carry out independent verifications or site visits.*

Third proposed Criterion 7: Consumer information regarding use and disposal

Comments	JRC Dir. B response
"Avoid any spillage to the environment" seems strange. The lubricant is released (to certain extent) into the environment when used.	**ACCEPTED** **Text has been reworded as:** "Avoid any spillage of unused product to the environment",
Typo/suggested clarification for Consumer information regarding use and disposal box: In the case of lubricants design to be sold to private end consumers, the following information (in text form or pictograms) shall be presented on the packaging/container (equivalent ways communicating the same information to the consumer may also be permitted)	**PARTIALLY ACCEPTED**

Third proposed Criterion 8: Information appearing on the EU Ecolabel

[64] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

Comments	JRC Dir. B response
OK for improvement but the sentence could be even more attractive depending on the category of lubricant and/or the amount of biobased components as is the case for EU Ecolabels for paints and tourism.	**AKNOLEDGED**
What is specific of lubricants is that for each intentionally added substance biodegradatioin and aquoues toxicity data must be submitted, independently of any possible environmental classification. Therefore this is the real focal point and much less hazardous substnces. In addition many lubricants irrespective of the type of base fluid are nowadays not classified. *Remove due to limited amount of hazardous substances.* *It is that biodegradation and aquatric toxicity data must be given for each stated substance which is really the added value of the EEL. This really means reduced harm for water and soil during use.*	**AKNOLEDGED**
Each ecolabel must include a technical performance criteria. Therefore performance is not a distinction. Remove text b.	**REJECTED** Detergents product group include a sentence like: *Tested for cleaning performance*
With regards: "X% of certified renewable ingredients used" (where relevant)", *It is the word or concept of bio that is referred to in Criterion 4.* *Is a biolubricant according to CEN/TR 16807:2017 (when relevant)*	This sentence refers to certified renewable ingredients, not to bio-based lubricants in general. However the applicant is free to advertise its product as "bio" in the package/container (not in the EU Ecolabel) as soon as they prove the minimum 25% renewable content is met. (criterion 4) Minimum certified renewability content is not mandatory. Criterion 4 requests only reporting activities with this regards (except for palm oil). This sentence allows the applicant to display the % of certified renewable ingredients, when used. This will promote the use of certified ingredients in case renewable ingredients are used in the formulation.
Rationale of proposed criterion text, 4th paragraph. The reference to the waste criteria of the Nordic Swan should be deleted from this report because Nordic Swan no longer includes lubricants as a Product Group: *Consider citing the Blue Angel requirements for advising consumers about the need to proper waste disposal instead*	**AKNOLEDGED**

Typo, Further research and main changes in the third proposal, 1st paragraph: *With the purpose of <u>making</u> this criterion more understandable, the first part of the sentence has been partially modified*	

Other comments

Comments	**JRC Dir. B response**
Our organization welcomes that there is no minimum mandatory content on the renewable origin of materials.	**ACCEPTED**
Several companies welcome the removal of a mandatory requirement for a minimum amount of renewable material in an ecolabel lubricant. They welcome the extension to alternative biodegradable, low-toxicity base stocks that are not necessarily based on renewable materials as being in line with other major environmental standards such as the German Blue Angel and the US Vessel General Permit. They also highlight the comments previously made by JRC and others that the existing life cycle data does not support the previously-held general opinion that renewable material must be environmentally beneficial.	
We agree with subsection "Further research and main changes in the third proposal" in Chapter 3.4 to delete the criterion concerning the amount of renewable material Removing the requirement for a minimum amount of renewable material in an EU Ecolabel lubricant is very reasonable.	
We believe that removing the requirement for a minimum amount of renewable material in an EU ecolabel lubricant would be a significant weakening of the ecolabel credentials in the eyes of the general public, and they would not necessarily understand the subtleties of the very limited LCA data cited by others to justify the removal of a minimum amount of renewable material from the criteria document. We note the apparent desire of COM/JRC to align the revised ecolabel criteria to be as close as possible with the German Blue Angel but the decision to remove renewable material <u>at this time</u> makes no sense, if only because we understand that UBA is considering including a minimum amount of renewable material at the next revision of the Blue Angel and will undertake a study to evaluate the environmental benefit of renewable material in lubricants against other types of non-renewable base stocks using LCA methodology. We therefore suggest a moratorium on omitting renewable material from the ecolabel criteria until more life cycle data ca be generated to conclusively demonstrate that they show no environmental benefit compared with other types of synthetic lubricant. A possible compromise position would be to require the inclusion of a lower amount of renewable material compared with the current standard for all three product categories. It is understandable that the EU ecolabel for lubricants does not want to be considered a surrogate for the CEN bio-lubricants standard but a nominal amount of 25% renewable material would appear to be a sensible compromise and avoid lubricant producers having to develop different fluids in order to be able to claim that they meet the ecolabel standard and can market the product as a bio-lubricant. Finally, it should be recognised by JRC that the removal of a minimum amount of renewable material from the ecolabel is another example of non-joined up EU regulation because the report published by the Commission Expert Group on Bio-based materials specifically cites the inclusion of renewable material in environmental standards as a key driver to a more circular, sustainable economy. This current decision therefore seriously undermines the Commission's own long-term initiative concerning the promotion of	**AKNOWLEDGE** The EU Ecolabel is a label that allows consumers to identify environmentally friendly high quality products and services. It is not a label specific for biobased products. Other ecolabels, such as Blue Angel, US-VGP and Swedish Standard, follow this approach and do not require a minimum percentage of renewable raw materials. The LCA review presented in the first technical performance was not conclusive and no evidence was found that supported biobased alternatives as superior environmental options. It is therefore proposed to follow a technology neutral approach. The deletion of criterion 4 on renewability opens the scope to all the lubricants that are able to

bio-based products in EU and a more circular economy, by removing the <u>only regulatory driver that exists in the EU economy</u>. *Despite the rejection of earlier comments from different stakeholders on having a minimum content of renewable material we continue to have the opinion that it is a mistake to completely omit this criterion from the revised lubricants standard. We understand that opposing views were submitted during the first and second consultations but the reason for deleting this criterion were not adequately explained in our opinion. In particular, a better approach would be to retain the need for a minimum amount of renewable raw material so that a comprehansive review can be initiated which would allow a more informed decision to be made at the next update arther than relying on unsubstantiated opinion. This should incude a targeted life cycle analysis comparing the environmental outputs of the various base fluids (renewable and non-renewable) under consideration. This is needed because the LCAs presented in the first technical report were inconclusive on this point, rather than providing a definitive answer either way. We accept that the ecolabel criteri for lubricants should not be seen as a surrogate for the bio-lubricants standard, we should like to point out the significant negative impact this action will have on the Commission's Lead Market Initiative to increase the uptake of bio-based products. Eliminating the need for renewable raw materials in the ecolabel criteria for lubricants removes the only EU regulatory policy instrument that currently creates a tangible market driver for biolubricants. Without the requirement to include a certain amount of biobased material in lubricants to meet the EU ecolabel criteria there will be zero incentive for EU lubricant producers to formulate with such material, because this is often more costly than non-biobased synthetic base fluids. For this reason we believe that JRC/Commission should take a leadership position and set a goal to influence other environmental standards rather than meekly fall into line behind other standards. What incentive would lubricant producers have to apply for the relatively costly EU ecolabel rather than another environmental standard when there now appears to be no differentiation? We also understand that UBA deferred a discussion on adding a renewability criterion to Blue Angel due to the absence of LCA data but that they are planning a study to evaluate the environmental credentials of bio-based lubricants. This is further justification for a moratorium on removing completely the requirement for a minimum amount of biobased material in ecolabelled lubricants.* *<u>A minimum of 25% by weight of ingredients in the final product should contain bio-based carbon from a renewable source (ALL, PLL and TLL)</u>*	comply with criteria 1, 2 and 3, and the renewability is not limiting the certification of a lubricant. Moreover, the scope is open to accommodate the development of new technologies in the lubricant industry.
I have only one significant comment regarding the third draft of the European Ecolabel for Lubricants and that concerns the removal of the requirement for minimum renewability for any of the product groups. *It seems to me that this recommendation is opposed to the stated intent of the European Union to promote a bio-based economy and initiatives moving towards an energy infrastructure with an increasing demand for more renewable energy and more efficiency. The recommendation on removing renewability content for EALs seems to be a backward step, out of line with other EU initiatives.* *Thanks for all your efforts during the last 12-18 months, I can certainly appreciate the huge task that you have taken on to facilitate the updating of the European Ecolabel for Lubricants*	

Overall, the draft is more clear and relevant. French licence holders seem to be more satisfied with this project (especially for greases, hazardous substances, consumer informations). *However, the inequality of treatment remains to the detriment of products of renewable origin, since it is necessary at least to justify a label RSPO, even to make an ASTM D6866 for the claim "bio".*	
The opening of the Ecolabel to all fluids continues to disconcert a licence holders, because it seems strange to place this eco-label on products of non-renewable fossil origin, at a time when the "renewable" origin becomes more and more visible. Furthermore, it is neglected that renewable materials do not emit CO2 to combustion or biodegradation since it has been absorbed from the atmosphere during the growth of the plant.	
I am working in a company offering both environmental considerate lubricants on synthetic petrochemical base as well as on renewable base. So, on one side, I appreciate the opportunity to approve formulations based on synthetic, petrochemical based ingredients – when they are biodegradable and non-toxic to the environment. But: the philosophy behind the Ecolabel as well as behind e.g. CEN-Standard 16807 was/(is still??) to offer opportunities to petrochemical and mineral oil based products on comparable performance level. *Petrochemical products are mainly made from mineral oil or natural gas in the very beginning. Little is developed on alternative, real renewable base. Although such products can show a longer service life in application – they are still used only once a time. You can't get more cycles out of these quantities from natural oil/gas reservoirs – which is still a drawback compared to renewable resources.* *Frankly speaking: recycling of such oils to start a new life cycle is an illusion. To make it profitable, waste oils are not separated due to their base, so recycled oils will keep the drawback of certain toxicity and non-biodegradability issues.* *So, to completely cut out renewability as a real criteria will lead to the situation that we will never see this criteria again – which is negative with regard to the starting philosophy of European lead market initiative. Couldn't we keep the criteria along to CEN EN 16807 at minimum 25% renewability as a criteria inside the Ecolabel to avoid complete loss of the "philosophy line"???*	
We do recommend to keep the existing limits for renewable content (>= 50% for ALL, >= 70 for TLL). Otherwise we expect massive confusion in the market. *The effective abolition of the actual "minimum RRM quota" is a fundamental impact for the existing products, because some types of petrochemical base oils are cheaper than bio-based synthetic esters - without being assessed in regard to sustainability. Moreover there is a realistic risk that new fluids based on pure hydrocarbons will become EEL awarded because the biodegradation tests have been again and again repeated until a borderline pass results is beeing obtained. For avoiding of this misuse it is recommended to provide a minimum RRM quota, because it can be assumed that the combination of biodegradability and renewability is of particular plausibility. If the existing limits for RRM content seem to high, please at least think of introducing of the 25% RRM limit of EN 16807 for the EEL.* *Please take also into account that relevant EEL awarded lubricants with significant volumes in the market had to gain important OEM approvals before they could be used widely spread in highly sophisticated applications. These approval processes took several years. Now these approvals for hydraulic and gear applications are finally granted and the market volumes are growing. Moreover in the final equipments materials especially seals have been changed to be compatible with*	

the ester based EEL lubricants. New EEL lubricants with other base oils will very likely not be compatible with these just recently introduced materials and cause a lot of problems in the field. *Any reformulation caused by revised EEL criteria will jeopardise the beginning success and set back the current market position of EEL lubricants. A modified formulation will immediately loose the OEM approval and has to get reapproved again which will consume a lot of time and money. It is very likely that some OEMs will be frustrated and reject new approval work. This situation should be avoided absolutely!* *In general, we do not understand the reason for totally cancelling the "minimum RRM quota": In every case, the complementary percentage in the lubricant formulation is open for petrochemical-based ingredients, thus avoiding any discrimination of base oils. The combination of renewable and petrochemically based raw materials meanwhile is largely accepted in the market.* *Our proposal: Don't disturb a relative small market by disruptive changes!*	
Use phase and End of life sections. The statements that 50% of all traitional lubricants/used oils are released/lost into the environment and that nearly 50% of all lubricants sold worldwide pollute the environment all need a citation/reference to be credible, or it should be stated that this is an estimated value (based on what) to avoid having subsequent reports cite this as a credible figure.	Unfortunately, LCA covering all types of lubricants and applications were not available at the time of the LCA review. LCA analysis was revealed difficulties to compare different base oils, because there are not a comparison covering all the base fluid considered and because the potential environmental impact of a base fluid depends on the impact category analysed. For this reason, during the second revision, a research was done to cover other environmental aspects not included in the LCA: biodegradability and toxicity of the lubricant. (See chapter 1.2.2 for mor3e information)
A reference is needed to justify the claim that all re-refined oils present 'high toxicity' otherwise this should be omitted. GEIR should be able to comment on this	
Flaws and omissions in a number of statements. *It is clear that this chapter is not a critical review where both the methods, the boundaries and the results of LCA-calculations are discussed from the relevant data in reports and scientific references.* *Only cradle-to-grave approaches are considered, impact of additives is unknown, life-time of lubricant has not been compared to time of the life-cyle of the base fluids, hot-spots are identified in vegetable oils in the cultivation phase and in mineral oils in the extraction phase.* *The report does not present the impacts from mineral versus bio-based raw materials in objective way. The impacts from mineral-oil based ingredients, e.g. from extraction stage, are not addressed sufficiently. Much focus is on agricultural stage.*	
In relation to the statement: It is important to note that not all renewable raw materials are sustainable, there are different issues influencing the sustainability of the bio-based products. *Only reference to vegetable oils is made. Other base fluids are not discussed. In addition not all means some. Which ones are those?* *Include those base oils that are sustainable and indicate clearly on which parameters this is based. This exclude verification by specific documents.* *This is an absolute statement derived from LCAs but LCAs compare only products.* *You must compare this with mineral oils and synthetic oils. The report needs to compare different base fluids on their " sustainability" aspect.*	.

The number of statements where no verification is required is quite large. These statements dimishes substantially the value of an ecolabel especially when these statements do not return in other criteria. *Reduce the number of statements where no verification is required* *Statements where no verification is required cannot be checked for whether applicants are in compliance or not.*	
The full chapter 4 refers only to vegetable oils. It really creates the message that the life-cycle of the vegetable oils is not sustainable. Since only reference to vegetable oils is made it must be concluded that the life-cycle of mineral oil is sustainable since this has not been addressed at all. Thii s all the more strange since the data are from LCA-calculations but these calculations only compare products. *Is on EU level accepted that the life-cylce of a vegetable oil is not sustainable and the life-cycle of a mineral oil is sustainable?*	
In relation to statement: Swedish Standard, follow this approach and do not require a minimum percentage of renewable raw materials *The Grease Swedish Standard A and B have a renewability criterium. Only B class greases with a 45% renewability are found.* *Several inconsistencies in the text is found in each Tech Report.* *At least the correct information and a critical approach is required indicating a critical review of existing LCA data inclusing the limitations of LCA calculations in general, development of options, advantages and disadvantages of these options also related to different positions of stakeholders. After such an approach one can try to formulate a revised criterion.*	
We doubt that public opinion is characterised by the idea that renewable material in EU Ecolabel lubricants provide benefits like some competitor companies mean. Otherwise relevant market surveys with adequate results need to be presented. *We agree that it is contentious whether the use of renewable material per se offers benefits to the environment without having relevant, high-quality LCA studies that cover the whole life cycle (cradle to grave).*	
The effect on the LuSC list is still confusing for me, and the time given for the adaptation seems a little bit undefined. In a comment you wrote "The transition period for most of the EU Ecolabel products is 1 year" In a practical point of view if a raw material producer adopts the new classifications in a year, the formulator of the lubricant will not have time to adopt the changed raw material classifications and limits. It would be more fair with the whole supply chain if you give 1 year for the LuSC list players and another one for the users of the listed materials.	Although there are some exceptions, 1 tear transition period is horizontal to all product Groups.
When the new criteria come into effect on 1st January 2019 it is assumed that it will also be necessary to reassess the LUSC substances. VSI requests that JRC/Commission should recognise the length of time it takes to develop lubricants, possibly including OEM approvals, and the level of investment necessary. In particular, it needs to be recognised that lubricant development has not been stopped whilst the new criteria have been discussed during the past 12 months. It is therefore	

inevitable that lubricants currently being developed to meet ecolabel are relying on LuSC substances that are approved according to the current criteria, and that at the time of submission may no longer qualify under the new criteria or the required study reports might not be available where repeat testing is necessary (e.g. new Log Kow measurements based on the updated criteria). It is therefore necessary that a review of the substances and products on the LuSC list should be performed quickly after the implementation date and that suitable transitional arrangements should be put in place where a substance/product no longer qualifies for LuSC listing. VSI suggests that a reasonable transitional period is at least until the end of 2020. We would also suggest that any lubricant that has been submitted for approval under the ecolabel scheme before that transitional date should be allowed to comply with the 'old' criteria and remain on the market until the next revision date.	
When the new criteria are put into effect, the LUSC substances will also be reassessed. In connection with the very long and time-consuming development of lubricants, possibly including OEM approvals, the situation that at the time of formulation substances are still included on the LUSC list, but at the time of submission, based on the refiews not be available for the simplified approach in terms of ecotoxicity, biodegradability and bioaccumulation. *It is therefore necessary that a review of the LUSC list be made immediately after the enforcement and that a transitional period be defined for a worse classification or intended removal. This transitional period should be at least until the end of 2020. All* *lubricants that have been submitted for certification until then should be able to carry the ECO label until the end of the new criteria period.*	
Under the new article 1, the lubricant groups are 3, while before there were 5 categories. T the LuSC list still shows the 5 categories. This could create difficulties or confusion when using the LuSC list. Should it be preferable not to modify the LuSC list then, it would be helpful to add in it a reference to the previous ecolabel decision (2011/381) and/or a definition of the 5 previous categories. Another possibility could be to write again the LuSC list by making reference to the new three groups as defined under article 1.	

When the new criteria come into effect on 1st January 2019 it is assumed that it will also be necessary to reassess the LUSC substances. VSI requests that JRC/Commission should recognise the length of time it takes to develop lubricants, possibly including OEM approvals, and the level of investment necessary. In particular, it needs to be recognised that lubricant development has not been stopped whilst the new criteria have been discussed during the past 12 months. It is therefore inevitable that lubricants currently being developed to meet ecolabel are relying on LuSC substances that are approved according to the current criteria, and that at the time of submission may no longer qualify under the new criteria or the required study reports might not be available where repeat testing is necessary (e.g. new Log Kow measurements based on the updated criteria). It is therefore necessary that a review of the substances and products on the LuSC list should be performed quickly after the implementation date and that suitable transitional arrangements should be put in place where a substance/product no longer qualifies for LuSC listing. VSI suggests that a reasonable transitional period is at least until the end of 2020. We would also suggest that any lubricant that has been submitted for approval under the ecolabel scheme before that transitional date should be allowed to comply with the 'old' criteria and remain on the market until the next revision date.	
Enough time should be allowed between publication of new adopted criteria for Ecolabel and the end of validity of current criteria. Will the existing EEL approvals be extended by 31st December 2019 if requested by the lubricant supplier? *Think of an adequate transition period*	
Considering changes in legislation, new evidence and data of substances/products currently listed on the LuSC list (and listed after Dec. 2018), what are the obligations of license carrier with respect to submitting updated information (in form of SDS, or similar)?	
Lubricants-Legal text Act. Article 4 *We can only accept a validity period of six years if it is connected to a work plan that states that the revision will be started in time, so that new criteria will be decided within the six years and that no prolongation is needed.*	**ACCEPTED**
Would it be possible to define in the user manual or in another way how can raw material manufacturers integrate their products in the Lusclist ?	**ACCEPTED**
is there a validity date of test reports ? Or do we consider that an old test report (10 years) could be accepted because it's chemical results ?	This question was posed in the CB forum and a CB mentioned that no date is requested and that available test reports are preferable to new data generation trough animal testing.
Reference to the Blue Angel was done several times through the document - Page 26, 27, 30, 32, 45, 46. *→ The overall impression is that the criteria are developed to ensure alignment with the Blue Angel (if not more restrictive*	Although there are similarities, EU Ecolabel continues having specificities:

in case of H phrases). What would differentiate the product certified with the Blue Angel label, from the one having EU Ecolabel?	• As far as possible horizontal EU Ecolabel hazardous criterion has been reflected in the revised criterion. • Thresholds on biodegradability and aquatic toxicity have been revised according to current EU Ecolabel licences. • Design /recyclability aspeccts have been addressed in new requirement.
The comparison of the new revised and the existing thresholds in force shows that the ambition level has considerably increased. *The requirements defined within the criteria 1 to 4 have undergone the most changes / modifications. Though there is a general effort made to promote labeling toward more sustainable and less hazardous products, does this indeed reflect the evolution of the market and the industry.*	**AKNOWLEDGE**
p. 63 in TR – it should be amended in the report that the standard for biosolvents is already completed	**ACCEPTED**

KJ-NA-29491-EN-N

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doi:10.2760/58736
ISBN 978-92-79-98176-0